

1           IN THE UNITED STATES DISTRICT COURT  
2           FOR THE NORTHERN DISTRICT OF OHIO  
3           EASTERN DIVISION

4                   -   -   -

5  
6           IN RE:    NATIONAL                   :   HON. DAN A.  
7           PRESCRIPTION OPIATE               :   POLSTER  
8           LITIGATION                         :  
9   :   MDL NO. 2804  
10          APPLIES TO ALL CASES               :  
11   :   CASE NO.  
12   :   17-MD-2804  
13   :  
14   :

15                   - HIGHLY CONFIDENTIAL -  
16          SUBJECT TO FURTHER CONFIDENTIALITY REVIEW  
17                   VOLUME I

18                   -   -   -

19                   May 16, 2019

20                   -   -   -

21                   Videotaped deposition of  
22          DR. SETH B. WHITELOW, taken pursuant to  
23          notice, was held at the offices of Golkow  
24          Litigation Services, One Liberty Place,  
25          1650 Market Street, Philadelphia,  
26          Pennsylvania beginning at 9:18 a.m., on  
27          the above date, before Michelle L. Gray,  
28          a Registered Professional Reporter,  
29          Certified Shorthand Reporter, Certified  
30          Realtime Reporter, and Notary Public.

31                   -   -   -

32                   GOLKOW LITIGATION SERVICES  
33                   877.370.3377 ph | 917.591.5672 fax  
34                   deps@golkow.com

<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES:</p> <p>2</p> <p>3 LEVIN PAPANTONIO THOMAS</p> <p>4 MITCHELL RAFFERTY &amp; PROCTOR, PA</p> <p>5 BY: BRANDON L. BOGLE, ESQ.</p> <p>6 316 South Baylen Street</p> <p>7 Suite 600</p> <p>8 Pensacola, Florida 32502</p> <p>9 (888) 435-7001</p> <p>10 bbogle@levinlaw.com</p> <p>11 - and -</p> <p>12 WEISMAN KENNEDY &amp; BERRIS CO LPA</p> <p>13 BY: DANIEL P. GOETZ, ESQ.</p> <p>14 1600 Midland Building</p> <p>15 101 W. Prospect Avenue</p> <p>16 Cleveland, Ohio 44115</p> <p>17 (216) 781-1111</p> <p>18 Dgoetz@weismanlaw.com</p> <p>19 - and -</p> <p>20 KELLER ROHRBACK, LLP</p> <p>21 BY: DEAN N. KAWAMOTO, ESQ.</p> <p>22 1201 Third Avenue</p> <p>23 Suite 3200</p> <p>24 Seattle, Washington 98101</p> <p>dkawamoto@kellerrohrback.com</p> <p>Representing the Plaintiffs</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: (Cont'd.)</p> <p>2</p> <p>3 BARTLIT BECK, LLP</p> <p>4 BY: KATHERINE M. SWIFT, ESQ.</p> <p>5 54 West Hubbard Street</p> <p>6 Chicago, Illinois 60654</p> <p>7 (312) 494-4440</p> <p>8 katherine.swift@bartlit-beck.com</p> <p>9 Representing the Defendant, Walgreens</p> <p>10 WILLIAMS &amp; CONNOLLY, LLP</p> <p>11 BY: JENNIFER G. WICHT, ESQ.</p> <p>12 BY: JOSHUA D. TULLY, ESQ.</p> <p>13 725 12th Street, NW</p> <p>14 Washington, D.C. 20005</p> <p>15 (202) 434-5148</p> <p>16 jwicht@wc.com</p> <p>17 jtully@wc.com</p> <p>18 Representing the Defendant, Cardinal</p> <p>19 Health</p> <p>20 ROPES &amp; GRAY, LLP</p> <p>21 BY: WILLIAM DAVISON, ESQ.</p> <p>22 BY: CASSANDRA A. LARUSSA, ESQ.</p> <p>23 Prudential Tower</p> <p>24 800 Boylston Street</p> <p>Boston, Massachusetts 02199</p> <p>(617) 951-7000</p> <p>william.davison@ropesgray.com</p> <p>cassandra.larussa@ropesgray.com</p> <p>Representing the Defendant,</p> <p>Mallinckrodt</p> <p>TUCKER ELLIS, LLP</p> <p>BY: JUSTIN E. RICE, ESQ.</p> <p>950 Main Avenue, Suite 1100</p> <p>Cleveland, Ohio 44113</p> <p>(216) 696-3670</p> <p>justin.rice@tuckerellis.com</p> <p>Representing the Defendant, Janssen and</p> <p>Johnson &amp; Johnson</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: (Cont'd.)</p> <p>2</p> <p>3 COVINGTON &amp; BURLING, LLP</p> <p>4 BY: CHRISTOPHER K. EPPICH, ESQ.</p> <p>5 1999 Avenue of the Stars</p> <p>6 Los Angeles, California 90067</p> <p>7 (424) 352-4764</p> <p>8 Ceppich@cov.com</p> <p>9 - and -</p> <p>10 COVINGTON &amp; BURLING, LLP</p> <p>11 BY: MEGHAN E. MONAGHAN, ESQ.</p> <p>12 850 Tenth Street, NW</p> <p>13 Suite 586N</p> <p>14 Washington, D.C. 20001</p> <p>15 mmonaghan@cov.com</p> <p>16 (202) 662-5110</p> <p>17 Representing the Defendant, McKesson</p> <p>18 Corporation</p> <p>19 JONES DAY</p> <p>20 BY: CLAIRE E. CASTLES, ESQ.</p> <p>21 555 South Flower Street</p> <p>22 Fiftieth Floor</p> <p>23 Los Angeles, California 90071</p> <p>24 (213) 489-3939</p> <p>Ccastles@jonesday.com</p> <p>Representing the Defendant, Walmart</p> <p>REED SMITH, LLP</p> <p>BY: SHANNON E. MCCLURE, ESQ.</p> <p>BY: JEFFREY R. MELTON, ESQ.</p> <p>Three Logan Square</p> <p>1717 Arch Street, Suite 3100</p> <p>Philadelphia, Pennsylvania 19103</p> <p>(215) 851-8226</p> <p>smcclure@reedsmith.com</p> <p>jmelton@reedsmith.com</p> <p>Representing the Defendant,</p> <p>AmerisourceBergen Drug Corporation</p>	<p style="text-align: right;">Page 5</p> <p>1 APPEARANCES: (Cont'd.)</p> <p>2</p> <p>3 BARNES &amp; THORNBURG, LLP</p> <p>4 BY: WILLIAM A. HAHN, ESQ.</p> <p>5 11 South Meridian Street</p> <p>6 Indianapolis, Indiana 46204</p> <p>7 (317) 236-1313</p> <p>8 William.hahn@btlaw.com</p> <p>9 Representing the Defendant, H.D. Smith</p> <p>10 MARCUS &amp; SHAPIRA, LLP</p> <p>11 BY: BENJAMIN A. KIFT, ESQ.</p> <p>12 One Oxford Centre, 35th Floor</p> <p>13 Pittsburgh, Pennsylvania 15219</p> <p>14 (412) 338-4683</p> <p>15 kift@marcus-shapira.com</p> <p>16 Representing the Defendant, HBC</p> <p>17 Service Company</p> <p>18 DECHERT, LLP</p> <p>19 BY: JACQUELINE D. HARRINGTON, ESQ.</p> <p>20 Three Bryant Park</p> <p>21 1095 Avenue of the Americas</p> <p>22 New York, New York 10036</p> <p>23 (212) 698-3500</p> <p>24 jacqueline.harrington@dechert.com</p> <p>Representing the Defendant, Purdue</p> <p>Pharmaceuticals</p> <p>FOLEY &amp; LARDNER, LLP</p> <p>BY: ANA M. FRANCISCO, ESQ.</p> <p>111 Huntington Avenue, Suite 2500</p> <p>Boston, Massachusetts 02199</p> <p>(617) 502-3281</p> <p>afrancisco@foley.com</p> <p>Representing Actavis Laboratories</p> <p>UT, Inc., Actavis Pharma, Inc.,</p> <p>ANDA, Inc., and Actavis, Inc.,</p> <p>(N/k/a Allergan Finance, LLC, Watson</p> <p>Laboratories, Inc.)</p>

Page 6

1 APPEARANCES: (Cont'd.)  
2  
3 **ARNOLD & PORTER KAYE SCHOLER, LLP**  
4 BY: ALLISON B. RUMSEY, ESQ.  
5 601 Massachusetts Avenue, NW  
6 Washington, D.C. 20001  
7 (202) 942-5095  
8 allison.rumsey@arnoldporter.com  
9 Representing the Defendants, Endo Health  
10 Solutions Endo Pharmaceuticals, Inc.; Par  
11 Pharmaceutical Companies, Inc. f/k/a Par  
12 Pharmaceutical Holdings, Inc.  
13  
14 **KIRKLAND & ELLIS, LLP**  
15 BY: ERICA B. ZOLNER, ESQ.  
16 300 North LaSalle Street  
17 Chicago, Illinois 60654  
18 (312) 862-3247  
19 erica.zolner@kirkland.com  
20 Representing the Defendant, Allergan  
21 Finance  
22  
23 **ZUCKERMAN SPAEDER, LLP**  
24 BY: PAUL B. HYNES, JR., ESQ.  
1800 M. Street NW, Suite 1000  
Washington, D.C. 20036  
(202) 778-1845  
phynes@zuckerman.com  
Representing the Defendant, CVS  
  
**MORGAN, LEWIS & BOCKIUS, LLP**  
BY: MELISSA M. COATES, ESQ.  
200 S. Biscayne Boulevard  
Suite 5300  
Miami, Florida 33131-2339  
(305) 415-3413  
melissa.coates@morganlewis.com  
Representing the Defendants, Teva  
Pharmaceuticals, Inc. Cephalon Inc,  
Watson Laboratories, Actavis LLC, Actavis  
Pharma, Inc.

Page 7

1 TELEPHONIC/STREAMING APPEARANCES:  
2 LEVIN PAPANTONIO THOMAS  
MITCHELL RAFFERTY & PROCTOR, PA  
3 BY: PAGE POERSCHKE, ESQ.  
4 BY: JEFF GADDY, ESQ.  
5 316 Baylen Street  
6 Pensacola, Florida 32502  
7 (850) 435-7000  
8 ppoerschke@levinlaw.com  
9 jgaddy@levinlaw.com  
10 - and -  
11 **WEISMAN KENNEDY & BERRIS CO LPA**  
12 BY: ERIC KENNEDY, ESQ.  
13 1600 Midland Building  
14 101 W. Prospect Avenue  
15 Cleveland, Ohio 44115  
16 (216) 781-1111  
17 ekennedy@weismanlaw.com  
18 Representing the Plaintiffs  
19  
20 **BRANSTETTER, STRANCH & JENNINGS, PLLC**  
21 BY: TRICIA HERZFELD, ESQ.  
22 223 Rosa L. Parks Avenue  
23 Suite 200  
24 Nashville, Tennessee 37203  
(615) 254-8801  
TriciaH@bsjfirm.com  
Representing the Tennessee Plaintiffs  
  
**WILLIAMS & CONNOLLY, LLP**  
BY: MIRANDA PETERSEN, ESQ.  
725 12th Street, NW  
Washington, D.C. 20005  
(202) 434-5148  
mpetersen@wc.com  
Representing the Defendant, Cardinal  
Health

Page 8

1 TELEPHONIC/STREAMING APPEARANCES:  
2 (Cont'd.)  
3  
4 **ROPES & GRAY, LLP**  
5 BY: FEIFEI (ANDREA) REN, ESQ.  
6 1211 Avenue of the Americas  
7 New York, NY 10036  
8 (212) 596-9303  
9 Andrea.ren@ropesgray.com  
10 Representing the Defendant,  
11 Mallinckrodt  
12  
13 **KIRKLAND & ELLIS, LLP**  
14 BY: KAITLYN COVERSTONE, ESQ.  
15 300 North LaSalle Street  
16 Chicago, Illinois 60654  
17 (312) 862-7184  
18 Kaitlyn.coverstone@kirkland.com  
19 Representing the Defendant, Allergan  
20  
21 **FOLEY & LARDNER, LLP**  
22 BY: KATY E. KOSKI, ESQ.  
23 111 Huntington Avenue, Suite 2500  
24 Boston, Massachusetts 02199  
(617) 502-3281  
Kkoski@foley.com  
Representing Actavis Laboratories  
UT, Inc., Actavis Pharma, Inc.,  
ANDA, Inc., and Actavis, Inc.,  
(n/k/a Allergan Finance, LLC, Watson  
Laboratories, Inc.)

Page 9

1 TELEPHONIC/STREAMING APPEARANCES:  
2 (Cont'd.)  
3  
4 **FOX ROTHSCHILD, LLP**  
5 BY: ZACHARY MARTIN, ESQ.  
6 2700 Kelly Road  
7 Suite 300  
8 Warrington, Pennsylvania 18976  
9 (215) 918-3680  
10 Zmartin@foxrothschild.com  
11 Representing the Defendant, Prescription  
12 Supply Inc.  
13  
14 **MORGAN LEWIS & BOCKIUS, LLP**  
15 BY: CATHERINE ESCHBACH, ESQ.  
16 1000 Louisiana Street, Suite 4000  
17 Houston, Texas 77002  
18 (713) 890-5719  
19 Catherine.eschbach@morganlewis.com  
20 Rite Aid of Maryland, Inc., doing  
21 business as Mid-Atlantic Customer Support  
22 Center  
23  
24 **LOCKE LORD, LLP**  
BY: LAUREN MORGAN FINCHER, ESQ.  
600 Congress Avenue, Suite 2200  
Austin, Texas 78701  
(512) 305-4843  
lfincher@lockelord.com  
Representing the Defendant, Henry Schein  
  
**BAILEY WYANT PLLC**  
BY: MICHAEL W. TAYLOR, ESQ.  
500 Virginia Street East  
Suite 600  
Charleston, West Virginia 25301  
(304) 345-4222  
mtaylor@baileywyant.com  
Representing the Defendant, West  
Virginia Board of Pharmacy

Page 10	
1	APPEARANCES: (Cont'd.)
2	
3	ALSO PRESENT:
4	
5	Brianna Poff - Paralegal
6	Cody Hartzog - Paralegal
7	Katie Mayo - Paralegal - (via telephone)
8	(Levin Papantonio)
9	
10	VIDEOTAPE TECHNICIAN:
11	David Lane
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	

Page 12	
1	
2	E X H I B I T S (Cont'd.)
3	
4	
5	NO. DESCRIPTION PAGE
6	Whitelaw-6 Memo, 10/20/05 191
7	Subject, Internet
8	Presentation with
9	McKesson Corp.
10	On 9/1/05
11	MCKMDL00496859-75
12	
13	Whitelaw-7 Diversion Control 223
14	Division, Tite 21
15	Of Federal Regulations
16	Part 1304
17	Whitelaw-8 Government Standards 277
18	Undermine Compliance
19	Efforts in Life
20	Science Companies
21	
22	Whitelaw-9 McKesson Regulatory 316
23	Investigative Report
24	MCKMDL00538943-46
1	
2	Whitelaw-10 Copy of Binder of 393
3	Dr. Seth B. Whitelaw
4	(Expert Report)
5	
6	Whitelaw-11 McKesson Handwritten 394
7	Notes, by Dr. Whitelaw
8	Whitelaw-12 Walgreens Handwritten 416
9	Notes, by Dr. Whitelaw
10	
11	Whitelaw-13 Chemical Handler's 512
12	Manual
13	January 2004
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	

Page 11	
1	
2	I N D E X
3	
4	
5	Testimony of:
6	DR. SETH B. WHITE LAW
7	By Mr. Eppich 15
8	By Ms. Swift 370
9	By Ms. Fincher 515
10	
11	E X H I B I T S
12	
13	
14	NO. DESCRIPTION PAGE
15	Whitelaw-1 Notice of Deposition 15
16	Whitelaw-2 Expert Report of 28
17	Dr. Seth B. Whitelaw
18	4/15/19
19	Whitelaw-3 Supplemental Report 28
20	Of Dr. Seth B.
21	Whitelaw, 5/10/19
22	Whitelaw-4 Diversion Control 124
23	Division, Tite 21
24	Of Federal Regulations
1	
2	Whitelaw-5 Report to the US 161
3	Attorney General
4	By the Suspicious
5	Orders Task Force
6	February 1999
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	

Page 13	
1	
2	D E P O S I T I O N S U P P O R T I N D E X
3	
4	
5	Direction to Witness Not to Answer
6	PAGE LINE
7	371 23
8	
9	Request for Production of Documents
10	PAGE LINE
11	None.
12	
13	Stipulations
14	PAGE LINE
15	None.
16	
17	Questions Marked
18	PAGE LINE
19	None.
20	
21	
22	
23	
24	

<p style="text-align: right;">Page 14</p> <p>1               - - -</p> <p>2               THE VIDEOGRAPHER: We are</p> <p>3               now on the record. My name is</p> <p>4               David Lane, videographer for</p> <p>5               Golkow Litigation Services.</p> <p>6               Today's date is May 16,</p> <p>7               2019. Our time is 9:18 a.m.</p> <p>8               This deposition is taking</p> <p>9               place in Philadelphia,</p> <p>10              Pennsylvania, in the matter of</p> <p>11              National Prescription opiate</p> <p>12              litigation MDL.</p> <p>13              Our deponent today is</p> <p>14              Dr. Seth Whitelaw.</p> <p>15              Our counsel will be noted on</p> <p>16              the stenographic record.</p> <p>17              The court reporter is</p> <p>18              Michelle Gray, who will now swear</p> <p>19              in our witness.</p> <p>20              - - -</p> <p>21              ... DR. SETH B. WHITELAW,</p> <p>22              having been first duly sworn, was</p> <p>23              examined and testified as follows:</p> <p>24              - - -</p>	<p style="text-align: right;">Page 16</p> <p>1 BY MR. EPPICH:</p> <p>2              Q. Dr. Whitelaw, you are</p> <p>3              appearing today as an expert witness</p> <p>4              retained by the plaintiffs?</p> <p>5              A. Yes, sir, I am.</p> <p>6              Q. Have you ever been deposed</p> <p>7              before?</p> <p>8              A. No, I have never been</p> <p>9              deposed.</p> <p>10             Q. Have you ever testified in</p> <p>11             court or any hearings before?</p> <p>12             A. No, sir, I have not</p> <p>13             testified in court or in hearings before.</p> <p>14             Q. Have you ever served as an</p> <p>15             expert witness before?</p> <p>16             A. No, sir.</p> <p>17             Q. Have you served as a</p> <p>18             consulting expert before?</p> <p>19             A. Yes, sir, I have served as a</p> <p>20             consulting expert for a number of</p> <p>21             companies over my career.</p> <p>22             Q. So because it's your first</p> <p>23             deposition I'll just go over a couple of</p> <p>24             the ground rules. I'll ask the</p>
<p style="text-align: right;">Page 15</p> <p>1               THE VIDEOGRAPHER: Please</p> <p>2               begin.</p> <p>3               - - -</p> <p>4               EXAMINATION</p> <p>5               - - -</p> <p>6 BY MR. EPPICH:</p> <p>7              Q. Good morning, Mr. Whitelaw.</p> <p>8              Thank you so much for coming in today.</p> <p>9              I introduced myself earlier.</p> <p>10             But again my name is Chris Eppich, and</p> <p>11             I'm an attorney for McKesson --</p> <p>12             A. Okay.</p> <p>13             Q. -- one of the distributor</p> <p>14             defendants in this litigation.</p> <p>15             A. Nice to meet you, Chris.</p> <p>16             Q. I'm going to be asking you a</p> <p>17             few questions today. And -- but let me,</p> <p>18             before I get there, let me go ahead and</p> <p>19             mark what's been -- what is your</p> <p>20             deposition notice. And I'll mark this as</p> <p>21             Exhibit Number 1.</p> <p>22             (Document marked for</p> <p>23             identification as Exhibit</p> <p>24             Whitelaw-1.)</p>	<p style="text-align: right;">Page 17</p> <p>1              questions, and you'll answer the</p> <p>2              questions. I'll let you finish your</p> <p>3              answers, but please let me finish my</p> <p>4              questions first.</p> <p>5              Your counsel's probably</p> <p>6              asked you to pause for a few seconds so</p> <p>7              he can get an objection in.</p> <p>8              Plaintiffs' counsel -- or</p> <p>9              excuse me. If -- if you have any --</p> <p>10             please ask me a question if you have any</p> <p>11             time -- if you have any at any time. If</p> <p>12             you don't -- if you don't have any</p> <p>13             concerns or questions with my questions,</p> <p>14             I'll assume you understood them.</p> <p>15             And if you need to take a</p> <p>16             break at any time, just go ahead and ask</p> <p>17             and we'll -- we can take a break. I just</p> <p>18             ask that if a question is pending, that</p> <p>19             you answer the question before we take a</p> <p>20             break.</p> <p>21             Sound good?</p> <p>22             A. Sounds very good.</p> <p>23             Q. When were you first</p> <p>24             contacted by the plaintiffs about</p>



<p style="text-align: right;">Page 18</p> <p>1 participating as an expert in this 2 litigation? 3 A. It would have been November, 4 December time frame, 2018. I can't be 5 precise on the date, but to the best of 6 my recollection. 7 Q. This was last year? 8 A. Yeah. This would have been 9 last year. 10 Q. And who contacted you? 11 A. I honestly don't remember 12 the first contact. But contact came from 13 the law firm of Seeger Weiss. 14 Q. Did you work with anyone on 15 Seeger Weiss on -- on your report, on 16 preparing your report? 17 A. Other than providing 18 invoices and things back and forth, no. 19 Q. Which plaintiffs' counsel 20 have you been working with? 21 A. I've worked with a number of 22 them -- 23 MR. BOGLE: Object to form. 24 You can answer.</p>	<p style="text-align: right;">Page 20</p> <p>1 hour for your work on this litigation? 2 A. \$400 an hour, sir, which is 3 my standard rate. 4 Q. And is that hourly rate, 5 does it apply to preparation of your 6 report and testifying? 7 A. Yes, sir, it does. 8 Q. How much time have you spent 9 on this case so far? 10 A. I have probably almost 11 1200 hours in. 12 Q. So you've billed 13 approximately \$480,000 to this case so 14 far; is that right? 15 A. If you count both billed and 16 unbilled time, yeah, that would be about 17 the right number. 18 Q. In these 1200 hours, what 19 have you done? 20 A. In these 1200 hours I've 21 actually produced a 300 -- the report 22 that you have in front of you which you 23 are well aware of. I have looked at six 24 different defendants, from a federal</p>
<p style="text-align: right;">Page 19</p> <p>1 BY MR. EPPICH: 2 Q. Can you tell me their names? 3 A. I can't give you a complete 4 list. 5 Q. Is Mr. Bogle one of those 6 counsel? 7 A. Yes, sir. 8 Q. And any other counsel in 9 this room? 10 A. All three of the 11 gentlemen -- the other two gentlemen that 12 are in the room. Mr. Goetz and 13 Mr. Kawamoto as well. 14 Q. Anyone else? 15 A. As I said, I don't have a 16 complete list in my head so I can't run 17 down a list for you. 18 Q. Before this case have you 19 worked with the Seeger Weiss firm before? 20 A. No, sir, I have not. 21 Q. Have you worked with the 22 Levin Papantonio firm before? 23 A. No, sir. 24 Q. How much are you billing per</p>	<p style="text-align: right;">Page 21</p> <p>1 sentencing guideline compliance 2 perspective. I have interviewed multiple 3 people on the plaintiffs' team. I have 4 asked for lots of documents. I have 5 reviewed those documents. I have asked 6 for additional questions, follow-up, et 7 cetera. 8 Again, pretty much the 9 standard work that I would do in any kind 10 of a compliance assessment or compliance 11 investigation or compliance audit, is 12 what I have done. 13 Then to take that 14 information and then to compile it into 15 what you see today. 16 Q. How much time did you spend 17 preparing your report? 18 A. I'm not sure I understand 19 your question, sir. 20 Q. Well, did you -- did you 21 write your report yourself? 22 A. Yes, sir, I did. 23 Q. How much time did you spend 24 writing your report?</p>

<p style="text-align: right;">Page 22</p> <p>1 A. It's hard to split it out 2 from the 1200 hours, sir, because again 3 it was a work -- the report is a work in 4 progress that comes about as you review 5 documents, make notes, et cetera, and 6 eventually come out to writing the 7 report. So I'm afraid I can't give you a 8 precise time.</p> <p>9 Q. How much time have you spent 10 preparing for your deposition today?</p> <p>11 A. Approximately 90 hours.</p> <p>12 Q. And how did you prepare for 13 your deposition?</p> <p>14 A. I spent a long time going 15 back over my report, re-reading it, 16 making sure that I understood what I had 17 written, looking at the documents that -- 18 that were underlying it.</p> <p>19 Basically, understanding how 20 the deposition process works, because as 21 you pointed out, I have not been deposed 22 before.</p> <p>23 Q. Did you prepare for this 24 deposition by yourself or with counsel?</p>	<p style="text-align: right;">Page 24</p> <p>1 preparation for today's deposition?</p> <p>2 A. I reviewed the new -- 3 obviously you have my supplemental 4 report. I reviewed the new developments 5 that had come out since I actually issued 6 the report. And also certain documents 7 are listed in there as well. Beyond that 8 I'm not sure -- I think that's the 9 complete universe to the best of my 10 recollection.</p> <p>11 Q. Did you review any documents 12 that are not listed in your report or 13 your supplemental report?</p> <p>14 A. Not that I --</p> <p>15 MR. BOGLE: Object to form. 16 THE WITNESS: Not that I 17 recall.</p> <p>18 BY MR. EPPICH:</p> <p>19 Q. Now, you list quite a few 20 documents in your reports. How did you 21 choose which documents to review, 22 particularly from the defendants?</p> <p>23 A. I followed the same uniform 24 approach, as I said to you before. I</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I prepared both, both on my 2 own and with assistance from counsel.</p> <p>3 Q. Which counsel did you meet 4 with to prepare for today's deposition?</p> <p>5 A. Certainly the three 6 gentlemen that are here. And again, I 7 don't have a complete list of everybody 8 else I've met with.</p> <p>9 Q. Do you recall how many 10 meetings you had with counsel in 11 preparation for today's deposition?</p> <p>12 A. My recollection we were -- 13 there were seven, somewhere between seven 14 and nine, something like that.</p> <p>15 Q. And about how long were 16 these meetings?</p> <p>17 A. They varied in length from, 18 you know, half a day to a couple hours.</p> <p>19 Q. So in preparation for 20 today's deposition, you mentioned a few 21 things you reviewed. You reviewed your 22 report, you reviewed some of the 23 documents that you cite. What -- what 24 other materials did you review in</p>	<p style="text-align: right;">Page 25</p> <p>1 followed the same uniform approach that I 2 do when I do any kind of a compliance 3 investigation, or compliance assessment.</p> <p>4 I use the federal sentencing 5 guidelines as my sort of framework. And 6 I asked counsel, in this case, serving 7 like I would a client, I need documents 8 in these particular areas, could you 9 please provide me with information that 10 relates to these particular areas. And 11 they provided me with those documents.</p> <p>12 If I was unclear or I didn't 13 get exactly -- it is an iterative 14 process. So if I was unclear or I didn't 15 get what I was looking for, I asked 16 further follow-up questions. I asked for 17 further information. Once I got that 18 information, I then reviewed it.</p> <p>19 Q. What were the original 20 categories of documents that you 21 requested from plaintiffs' counsel?</p> <p>22 A. We can turn to my report and 23 we can go down the eight elements of the 24 federal sentencing guidelines if you'd</p>

<p style="text-align: right;">Page 26</p> <p>1 like.</p> <p>2 Q. We can do that in a few</p> <p>3 minutes. But sitting here, just now, do</p> <p>4 you recall any of the categories of</p> <p>5 documents?</p> <p>6 MR. BOGLE: If you need to</p> <p>7 refer to your report, you can.</p> <p>8 THE WITNESS: I'm going to</p> <p>9 refer to my report. Since he</p> <p>10 wants to go down the categories,</p> <p>11 let's go down the categories.</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. Why don't we go through that</p> <p>14 later. I'll strike the question.</p> <p>15 Did you review any</p> <p>16 deposition transcripts?</p> <p>17 A. Yes, sir, I did.</p> <p>18 Q. Which -- did you read the</p> <p>19 entire transcripts or just portions of</p> <p>20 the transcripts?</p> <p>21 A. Depended on the witnesses.</p> <p>22 I read some completely from beginning to</p> <p>23 end and I read some that -- substantial</p> <p>24 portions.</p>	<p style="text-align: right;">Page 28</p> <p>1 because I was able to put the deposition</p> <p>2 up. And then you're talking about a</p> <p>3 certain -- you know, certain document, I</p> <p>4 put the document up. And so I can see</p> <p>5 the back and forth. Again, that's the</p> <p>6 only way that I'm going to get the</p> <p>7 context of what was going on in those</p> <p>8 depositions.</p> <p>9 Q. Why don't we go ahead and</p> <p>10 mark your report.</p> <p>11 (Document marked for</p> <p>12 identification as Exhibit</p> <p>13 Whitelaw-2.)</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. I'll mark your report, your</p> <p>16 expert report that was served on</p> <p>17 April 15th as Exhibit Number 2 and your</p> <p>18 supplemental that was served on May 10th</p> <p>19 as Exhibit 3.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Whitelaw-3.)</p> <p>23 MR. BOGLE: So one question</p> <p>24 here just so I'm clear. These two</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. And how did you determine</p> <p>2 whether or not to read the entire</p> <p>3 deposition transcript or just a portion?</p> <p>4 A. I made a judgment call based</p> <p>5 on what I was looking for. And thanks to</p> <p>6 the court reporter's keyword searches, it</p> <p>7 makes it fairly easy to say if I'm</p> <p>8 looking for a particular topic. Let's</p> <p>9 say I'm looking for training. I can go</p> <p>10 through the deposition and look at all</p> <p>11 the instances of where training was. And</p> <p>12 read before and after and what was the</p> <p>13 context of the question and try to</p> <p>14 understand what it was.</p> <p>15 Q. Did plaintiffs' counsel</p> <p>16 point you to any specific portions of</p> <p>17 deposition transcripts?</p> <p>18 A. Not that I recall.</p> <p>19 Q. Did you review the exhibits</p> <p>20 to each of the depositions?</p> <p>21 A. I didn't review every</p> <p>22 exhibit. Did I review exhibits, yes.</p> <p>23 Actually my method, Chris, was -- thank</p> <p>24 God for a 34-inch monitor that I had,</p>	<p style="text-align: right;">Page 29</p> <p>1 combined are Exhibit 2; is that</p> <p>2 right?</p> <p>3 MR. EPPICH: That's right.</p> <p>4 At the break we'll combine them.</p> <p>5 MR. BOGLE: That's fine.</p> <p>6 Just to make sure we're clear. So</p> <p>7 that's the report entirely there,</p> <p>8 I think. And that's the</p> <p>9 supplemental.</p> <p>10 THE WITNESS: Thank you,</p> <p>11 sir.</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. Before you, Dr. Whitelaw,</p> <p>14 you have copies of your original report</p> <p>15 from April 15th and your supplemental</p> <p>16 report from May 10th.</p> <p>17 A. I do.</p> <p>18 Q. Do you have -- sitting here</p> <p>19 today, do you have any plans to further</p> <p>20 supplement your expert reports?</p> <p>21 MR. BOGLE: Object to form.</p> <p>22 THE WITNESS: It's awful</p> <p>23 hard to tell you whether or not I</p> <p>24 do. It depends on if there are</p>



<p style="text-align: right;">Page 30</p> <p>1 new developments that are relevant          2 to the work that I've already          3 done, so...</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. But these reports express --          6 represent your complete set of opinions          7 in this case; is that true?</p> <p>8 A. At this moment in time, as          9 you'll notice in my original report, I          10 reserve the right to supplement the          11 report should new and additional          12 information come to light that's relevant          13 to the work that I've done.</p> <p>14 Q. Do you have any changes to          15 make to either of your reports sitting          16 here today?</p> <p>17 A. Not that I can think of.</p> <p>18 Q. You still hold all of the          19 opinions expressed in these reports?</p> <p>20 A. Yes, sir, I do.</p> <p>21 Q. In writing your report, did          22 you report -- did you write the first          23 draft of your report?</p> <p>24 A. Chris, I wrote every draft</p>	<p style="text-align: right;">Page 32</p> <p>1 exclusions.</p> <p>2 Q. Did you share drafts with          3 them?</p> <p>4 A. Yes, I did share drafts with          5 counsel.</p> <p>6 Q. How did you share drafts          7 with counsel? Was it through the e-mail?</p> <p>8 A. Electronically.</p> <p>9 Q. Was that through e-mail?</p> <p>10 A. Yes, I believe so.</p> <p>11 Q. So you would send a copy of          12 your draft to plaintiffs' counsel for          13 them to review, and they would -- they          14 would respond by --</p> <p>15 A. I would tell them what I was          16 doing, so they can see the work that was          17 being done, were we on track, were we on          18 time, yes. But if what you're getting at          19 is whether or not counsel directed me on          20 how to actually write this report, the          21 answer is absolutely not.</p> <p>22 Q. When did you form the          23 opinions that are expressed in your          24 report?</p>
<p style="text-align: right;">Page 31</p> <p>1 of this report.</p> <p>2 Q. Did plaintiffs' counsel          3 comment or offer revisions to your report          4 at any time?</p> <p>5 A. Plaintiffs' counsel and I          6 had conversations to make sure what I saw          7 or what I thought I saw and I had gotten          8 the facts accurately or was I missing          9 something, yes.</p> <p>10 Did they tell me what to          11 write? Absolutely not. These are my          12 words. This is my work. And this is how          13 I always do my work.</p> <p>14 Q. Did -- did they offer you          15 any edits to any of the lines or          16 sentences in your report?</p> <p>17 A. Perhaps they may have. They          18 may have said, again, to make sure we          19 were factually correct. If I got a date          20 wrong, a Bates number wrong, yeah. I'm          21 sure they did.</p> <p>22 Q. Did they ask you to exclude          23 any sections or portions of your report?</p> <p>24 A. No, sir. There was no</p>	<p style="text-align: right;">Page 33</p> <p>1 MR. BOGLE: Object to form.          2 Vague and ambiguous.</p> <p>3 THE WITNESS: Could you be          4 more clear of the question that          5 you're asking?</p> <p>6 BY MR. EPPICH:</p> <p>7 Q. When did you start to write          8 the report? When did you put pen to          9 paper, is what I'm really asking.</p> <p>10 A. Is that what you're really          11 asking? Okay. I can tell you when I          12 started to put pen to paper. Probably          13 put pen to paper beginning almost day one          14 because the federal sentencing          15 guidelines, standards were there.          16 Controlled substances standards were          17 there. Start with the standards.</p> <p>18 So have to write. How do          19 you describe it. How do I put it in          20 terms that the judge and the court can          21 understand. How to explain it.</p> <p>22 But as far as forming my          23 opinions about each individual client,          24 Chris, after I finished my review of the</p>

Page 34

1 documents and interviews, et cetera, and  
2 reading deposition testimony, that's  
3 where -- where those opinions came about.  
4 Q. So you mentioned earlier  
5 that you spoke with plaintiffs' counsel  
6 about your report. Did you speak with  
7 anyone from Cuyahoga County?  
8 A. Specifically in Cuyahoga  
9 County?  
10 Q. Well, any -- anyone that  
11 works for the government, for the state,  
12 for police departments. Any -- any  
13 government agencies. Anyone from  
14 Cuyahoga County?  
15 A. No, sir, I did not.  
16 Q. Did you speak with anyone  
17 from Summit County?  
18 A. Again, same answer; no, I --  
19 sir, I did not.  
20 Q. How about the city of Akron?  
21 A. No, sir, I did not.  
22 Q. City of Cleveland?  
23 A. No, sir. I did not speak  
24 with anybody from the city of Cleveland.

Page 35

1 Q. Have you spoken with any of  
2 plaintiffs' other experts?  
3 A. Yes, I have.  
4 Q. Who have you -- which --  
5 which other plaintiffs' experts have you  
6 spoken with?  
7 A. I spoke at length with  
8 Mr. Rafalski. We had several  
9 conversations. Again, his expertise as a  
10 DEA agent and certainly what DEA was  
11 thinking at the time and how an inspector  
12 would approach the controlled substances  
13 regulations, were of particular  
14 importance and use to me as far as  
15 understanding what I was looking at, and  
16 having an understanding of the DEA's  
17 positions on certain topics.  
18 Q. Did you speak with any of  
19 other -- any other of plaintiffs'  
20 experts?  
21 A. Not that I can recall, sir.  
22 Q. Do you know Craig McCann?  
23 A. I don't know Craig McCann.  
24 I know of Craig McCann.

Page 36

1 Q. Have you spoken with  
2 Mr. McCann?  
3 A. No, sir, I have not.  
4 Q. Did you provide Mr. McCann  
5 with any of your analysis or work?  
6 A. No.  
7 Q. Did you provide Mr. Rafalski  
8 with any of your analysis or work?  
9 A. No, I did not provide  
10 Mr. Rafalski with any of my analysis or  
11 work. I asked him questions, we had  
12 telephone conversations.  
13 Q. In preparing your report or  
14 reaching any of your opinions, did you  
15 speak with anyone from the DEA?  
16 A. Well, I would assume  
17 Mr. Rafalski counsel's former DEA, but if  
18 you're asking me anybody -- are you  
19 asking me the question of anybody  
20 currently employed by DEA?  
21 Q. Yes, sir.  
22 A. No, sir, I did not speak to  
23 anybody who is currently employed with  
24 the Drug Enforcement Administration.

Page 37

1 Q. And other than Mr. Rafalski,  
2 did you speak with anyone who was  
3 formerly employed by the DEA in reaching  
4 your opinions?  
5 A. No, sir, he was the only one  
6 I spoke with.  
7 Q. Last summer did you attend a  
8 meeting with plaintiffs' counsel and  
9 several of the other expert witnesses in  
10 this case?  
11 A. Last summer?  
12 Q. Last summer.  
13 A. Can you -- can you be more  
14 specific on last summer?  
15 Q. June 2018.  
16 A. No, sir, I did not. As I  
17 said to you, I wasn't -- they didn't  
18 reach out to me until November 2018.  
19 Q. Have you attended any -- any  
20 meetings with plaintiffs' counsel and  
21 other plaintiffs' experts in this case  
22 since you were retained in November of  
23 2018?  
24 A. Could you say that question

<p style="text-align: right;">Page 38</p> <p>1 again?</p> <p>2 Q. Yes, sir.</p> <p>3 Have you attended any</p> <p>4 meetings with plaintiffs' counsel and the</p> <p>5 other plaintiffs' experts in this case</p> <p>6 since you were retained in November 2018?</p> <p>7 A. Again, with the exception of</p> <p>8 my conversations with Mr. Rafalski, the</p> <p>9 answer is no.</p> <p>10 Q. Now, earlier you mentioned</p> <p>11 that you interviewed people to prepare</p> <p>12 your report. Other than Mr. Rafalski,</p> <p>13 was there anyone else that you</p> <p>14 interviewed?</p> <p>15 A. When I meant interview, I</p> <p>16 had conversations with various members of</p> <p>17 the plaintiffs' counsel asking, this is</p> <p>18 what I'm looking for, can you please</p> <p>19 provide me with this information.</p> <p>20 Q. Okay. Just -- just so I'm</p> <p>21 clear. You -- you have spoken with</p> <p>22 plaintiffs' counsel and you've spoken</p> <p>23 with Mr. Rafalski --</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 40</p> <p>1 anti-diversion efforts of a manufacturer</p> <p>2 or a distributor, including" --</p> <p>3 "including their suspicious order</p> <p>4 monitoring programs. We also discussed</p> <p>5 what the DEA generally considers an</p> <p>6 effective controlled substances</p> <p>7 compliance program for a prudent</p> <p>8 registrant."</p> <p>9 Do you see that, sir?</p> <p>10 A. Yes, sir. I see the -- I</p> <p>11 see that paragraph, yes.</p> <p>12 Q. Did Mr. Rafalski explain to</p> <p>13 you that he was prevented from sharing</p> <p>14 any non-public information he had learned</p> <p>15 during his time at the DEA based on an</p> <p>16 instruction from the Department of</p> <p>17 Justice?</p> <p>18 A. Mr. Rafalski expressed that</p> <p>19 to me, yes. And he also made it -- we</p> <p>20 also made it clear that we were not going</p> <p>21 to be asking about specific defendants.</p> <p>22 We were asking general questions in</p> <p>23 the -- about what a prudent registrant or</p> <p>24 manufacturer needed to do.</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. -- in preparing your report.</p> <p>2 And -- and no one else?</p> <p>3 A. That is correct.</p> <p>4 Q. Okay. Thank you.</p> <p>5 Why don't we turn to Page 4</p> <p>6 in your expert report, Exhibit 2.</p> <p>7 A. Yeah. In particular is</p> <p>8 there someplace you want me to look?</p> <p>9 Q. Yes --</p> <p>10 MR. BOGLE: He'll guide you.</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. Just give me a minute --</p> <p>13 give me a minute to flip the pages.</p> <p>14 Dr. Whitelaw, I'm on Page 4,</p> <p>15 the second full paragraph. And I'm</p> <p>16 looking at the second line of that</p> <p>17 paragraph.</p> <p>18 This is discussing your</p> <p>19 consultation with Mr. Rafalski.</p> <p>20 You say, "I discussed with</p> <p>21 him how the DEA applies the Controlled</p> <p>22 Substances Act, the accompanying</p> <p>23 regulations, and the agency's guidance</p> <p>24 when inspecting the controlled substances</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. What did Mr. Rafalski tell</p> <p>2 you about how the DEA applied the -- the</p> <p>3 Controlled Substances Act?</p> <p>4 A. Could you be more specific</p> <p>5 in what you're asking me?</p> <p>6 Q. No, I'd appreciate if you</p> <p>7 could answer that question.</p> <p>8 A. It's a pretty -- it's a</p> <p>9 pretty broad --</p> <p>10 I'm afraid you're asking a</p> <p>11 very broad question.</p> <p>12 Q. Did you talk about the</p> <p>13 Controlled Substances Act?</p> <p>14 A. Yes, we did.</p> <p>15 Q. And what did you discuss?</p> <p>16 A. The elements of what DEA</p> <p>17 considered to be an effective</p> <p>18 anti-diversion program. What he -- what</p> <p>19 is generally seen out there. What -- we</p> <p>20 talked about variances under guidance</p> <p>21 that was there. I mean, it was a broad</p> <p>22 far-reaching conversation.</p> <p>23 Q. And did he talk to you about</p> <p>24 how the DEA applies the regulations to</p>

<p style="text-align: right;">Page 42</p> <p>1 registrants?</p> <p>2 A. Again, I'm not sure I</p> <p>3 understand the question.</p> <p>4 Q. Well, you're familiar with</p> <p>5 suspicious order monitoring programs,</p> <p>6 aren't you?</p> <p>7 A. Yes, I am.</p> <p>8 Q. And did Mr. Rafalski explain</p> <p>9 to you how the DEA applies the Controlled</p> <p>10 Substances Act to monitor or evaluate</p> <p>11 suspicious order monitoring systems?</p> <p>12 A. We talked about how to -- we</p> <p>13 talked about --</p> <p>14 MR. BOGLE: Just wait till</p> <p>15 he finishes the question.</p> <p>16 THE WITNESS: I'm sorry.</p> <p>17 MR. BOGLE: Go ahead.</p> <p>18 THE WITNESS: I'm not</p> <p>19 exactly sure what you're asking</p> <p>20 me.</p> <p>21 Are you asking me do I know,</p> <p>22 did we discuss the fact that the</p> <p>23 DEA conducts inspections of</p> <p>24 registrants and that sort of</p>	<p style="text-align: right;">Page 44</p> <p>1 them in general. We did not talk about</p> <p>2 them in specifics. If you're asking me</p> <p>3 did he show me a specific section in a</p> <p>4 specific manual? No, he did not.</p> <p>5 Q. Do you remember anything</p> <p>6 about the substance of your discussion</p> <p>7 with him about the DEA process for</p> <p>8 conducting an inspection of a registrant?</p> <p>9 A. As I told you, we talked in</p> <p>10 general terms. We did not talk in</p> <p>11 specifics about, you filed this paper on</p> <p>12 this date, you walk in, you show your</p> <p>13 credentials, et cetera.</p> <p>14 Q. I'm just trying to</p> <p>15 understand what -- where -- what was the</p> <p>16 general terms, general discussion that</p> <p>17 you had, the substance of those general</p> <p>18 discussions. That's all I'm looking for.</p> <p>19 A. Well, the general substance</p> <p>20 of those discussions were around, again,</p> <p>21 what would you expect to see from a good</p> <p>22 suspicious order monitoring program, what</p> <p>23 would DEA expect from that when DEA talks</p> <p>24 about when -- what's -- when discovered</p>
<p style="text-align: right;">Page 43</p> <p>1 thing? Yes, we did.</p> <p>2 Beyond that, I'm not sure</p> <p>3 exactly what you're looking for or</p> <p>4 I really, truly do not understand</p> <p>5 your question.</p> <p>6 BY MR. EPPICH:</p> <p>7 Q. And what did Mr. Rafalski</p> <p>8 tell you about how the DEA conducts</p> <p>9 inspections?</p> <p>10 A. Mr. Rafalski told me that</p> <p>11 they do -- there are four cause and</p> <p>12 routine inspections that are done, both.</p> <p>13 We didn't get into specifics of how they</p> <p>14 choose registrants over another. We just</p> <p>15 generally talked about an inspection.</p> <p>16 Q. Did he tell you what the DEA</p> <p>17 does during each of those inspections?</p> <p>18 A. We did not get into</p> <p>19 precisely exactly how you walk through</p> <p>20 and do an inspection, no.</p> <p>21 Q. He didn't tell you about any</p> <p>22 of the DEA procedures or methods for</p> <p>23 conducting those inspections?</p> <p>24 A. We probably talked about</p>	<p style="text-align: right;">Page 45</p> <p>1 and what do they generally look for. How</p> <p>2 do you -- you know, what do they</p> <p>3 generally look for when they're looking</p> <p>4 at thresholds in general.</p> <p>5 Again, it was a very general</p> <p>6 broad-brush discussion.</p> <p>7 Q. And what did Mr. Rafalski</p> <p>8 say the DEA was looking for in a good</p> <p>9 suspicious order monitoring program?</p> <p>10 A. Well, it's incorporated in</p> <p>11 the report. We can go through it in</p> <p>12 Section 6 if you'd like. Because it's</p> <p>13 both my understanding of what should be</p> <p>14 there, as well as, you know, as a</p> <p>15 reflection of those conversations. I</p> <p>16 can't point to you specific Point A,</p> <p>17 Point B, Point C, but we can certainly</p> <p>18 walk through Section 6 if you'd like.</p> <p>19 Q. You can't recall any of the</p> <p>20 points that Mr. Rafalski provided to you?</p> <p>21 A. No, sir. I don't think</p> <p>22 Mr. Rafalski, quote-unquote, provided me</p> <p>23 with any points. I think it was</p> <p>24 conversation around this is what I'm</p>

<p style="text-align: right;">Page 46</p> <p>1 seeing, this is what I would expect to  2 see. He said, yes, that's what we would  3 expect to see as well. It was that kind  4 of a conversation.  5 Q. Did Mr. Rafalski discuss  6 with you the DEA's legal guidance when  7 inspecting a manufacturer or  8 distributor's controlled substance  9 anti-diversion efforts?  10 A. Again, we discussed it  11 briefly as to what it -- what it was,  12 what was out there, had I -- my question  13 to him was had I seen the full panoply of  14 things that I needed to see. Again, did  15 we get into the exact nuts and bolts of  16 every letter? No, we did not.  17 Q. What letters are you  18 referring to?  19 A. I'm referring to the  20 Rannazzisi letters as part of guidance.  21 I mean, there were a lot of things of  22 guidance that we could have talked about.  23 But that's --  24 Q. Did Mr. Rafalski tell you</p>	<p style="text-align: right;">Page 48</p> <p>1 December?  2 MR. BOGLE: Object to form.  3 Asked and answered.  4 THE WITNESS: I honestly  5 don't remember the dates for you,  6 sir.  7 BY MR. EPPICH:  8 Q. Do you remember how long the  9 conversation lasted?  10 A. Not off the top of my head,  11 I don't.  12 Q. Was it in person or on the  13 phone?  14 A. It was on the phone. That,  15 I do remember. He's in -- I don't know  16 where he lives. But he wasn't -- we're  17 not near each other. Let's just put it  18 that way.  19 Q. And were plaintiffs' counsel  20 present for these discussions?  21 A. Yes.  22 Q. Which plaintiffs' counsel?  23 A. Well, I know Mr. Bogle was  24 present. And beyond that I don't rightly</p>
<p style="text-align: right;">Page 47</p> <p>1 that the information he provided you on  2 these topics was based on his experience  3 and training at the DEA?  4 A. Yes. Actually, he did. He  5 told me that it was based on his  6 experience and what he had encountered in  7 working for DEA, yes.  8 Q. And it was your  9 understanding that Mr. Rafalski was  10 drawing on his experience and training  11 from his time at the DEA when he shared  12 this information with you?  13 A. That was my understanding,  14 yes, sir.  15 Q. How many conversations did  16 you have with Mr. Rafalski?  17 A. I think it was four.  18 Q. Do you remember when the  19 first conversation you had with  20 Mr. Rafalski took place?  21 A. No, sir. I can't. I don't  22 have precise dates for you. I'm sorry.  23 Q. Was it in January or  24 February, or was it earlier in November,</p>	<p style="text-align: right;">Page 49</p> <p>1 recall.  2 Q. Was Mr. Bogle present for  3 all of your conversations with  4 Mr. Rafalski?  5 A. Yes, I believe he was.  6 Q. Do you recall any other  7 attorneys from the plaintiffs' side that  8 were present for any of your  9 conversations with Mr. Rafalski?  10 A. As I said to you previously,  11 no, sir, I don't.  12 Q. Was Mr. Mike Fuller present?  13 A. I don't rightly recall, sir.  14 Q. Was Ms. Amy Quezon?  15 A. Again, I don't recall the  16 names of the counsel from the -- the  17 other counsel that might have been  18 present during the meeting.  19 Q. Did you have any in-person  20 conversations with Mr. Rafalski?  21 A. No, sir, I did not.  22 Q. They were all by the phone?  23 A. They were all by phone.  24 Q. Dr. Whitelaw, if you could</p>



Page 50

1 turn to Appendix 1 of your first report.  
 2 A. Okay.  
 3 Q. Exhibit 2. This is on Page  
 4 259.  
 5 A. Yes, sir.  
 6 Q. Is this a complete list of  
 7 all the materials you considered in  
 8 forming your opinions in your April 15  
 9 report?  
 10 A. To the best of my knowledge,  
 11 it is complete, yes.  
 12 Q. Did you consider anything  
 13 that's not listed in this -- in this  
 14 report -- excuse me -- in Appendix 1?  
 15 A. I believe, as I just  
 16 answered to you, I believe it's fully --  
 17 it's full and complete.  
 18 Q. And how were the documents  
 19 on this list selected?  
 20 MR. BOGLE: Objection.  
 21 Asked and answered.  
 22 THE WITNESS: Well, we can  
 23 go back over it again. But we'll  
 24 take it from the top.

Page 51

1 I start with the federal  
 2 sentencing guidelines. They're  
 3 the eight elements in the federal  
 4 sentencing guidelines.  
 5 I asked counsel with each  
 6 defendant that I was asked to look  
 7 at, I'm looking for documents like  
 8 this. Do we have any evidence of  
 9 this? I'd like to see standard  
 10 operating procedures, please. I'd  
 11 like to see this. They produced  
 12 what they had.  
 13 If I was confused or didn't  
 14 understand what I got or I thought  
 15 there might be more, I said this  
 16 is what I'm looking for. We  
 17 worked back and forth until I  
 18 thought I had a complete --  
 19 complete inventory of the  
 20 documents I would need to see to  
 21 be able to render my opinion.  
 22 BY MR. EPPICH:  
 23 Q. And the plaintiffs' counsel  
 24 provided all these documents to you in

Page 52

1 response to your request, correct?  
 2 A. There are documents that are  
 3 in here listed that actually are publicly  
 4 available documents from the web that I  
 5 was able to pull down, and those are  
 6 noted separately.  
 7 But if you're talking about  
 8 in section -- are we talking just Section  
 9 A?  
 10 Q. Yes, sir.  
 11 A. Okay. The documents in  
 12 Section A were provided to me by counsel  
 13 at my direct request.  
 14 Q. If you can turn to Page 276.  
 15 Pardon me. Let's start with 275. Page  
 16 275.  
 17 A. Hang on a second. Hang on a  
 18 second. I'm getting there.  
 19 Q. On Page 275, there's a  
 20 Section F, defendant discovery responses.  
 21 A. Mm-hmm.  
 22 Q. Did plaintiffs provide these  
 23 to you upon your request?  
 24 A. Yes.

Page 53

1 Q. And looking at Page 276,  
 2 Section G, corporate witness depositions.  
 3 In response to your  
 4 requests, plaintiffs selected these  
 5 deposition transcripts and sent these to  
 6 you to review?  
 7 A. If they fit the topics I was  
 8 looking for, and the end documents that  
 9 supported my understanding of what was  
 10 transpiring, these would be the witnesses  
 11 I would have interviewed in a company had  
 12 I been able to do live witness, you know,  
 13 interactions, yeah.  
 14 Q. And in Section H, on  
 15 Page 277, there's some third-party  
 16 witness depositions. Did plaintiffs'  
 17 counsel provide these deposition  
 18 transcripts to you in response to your  
 19 request?  
 20 A. Yes.  
 21 Q. Now, at any time did the  
 22 plaintiffs' counsel provide to you a  
 23 complete list of corporate witnesses or  
 24 third-party witnesses that had been

<p style="text-align: right;">Page 54</p> <p>1 deposited in this case?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: I don't recall</p> <p>4 seeing a complete list. But again</p> <p>5 I was working defendant by</p> <p>6 defendant. So I'm not sure I saw</p> <p>7 a unified list, if that's what</p> <p>8 you're asking.</p> <p>9 BY MR. EPPICH:</p> <p>10 Q. You reviewed additional</p> <p>11 materials in support of your May 10</p> <p>12 supplemental report, correct?</p> <p>13 A. I did.</p> <p>14 Is there something in</p> <p>15 particular you'd like to look at?</p> <p>16 Q. You reviewed McKesson due</p> <p>17 diligence files; is that correct?</p> <p>18 And for your reference, I'm</p> <p>19 on Appendix A of your supplemental</p> <p>20 report, Exhibit 3, Page 11.</p> <p>21 A. Thank you. Thank you. I'll</p> <p>22 go there.</p> <p>23 MR. BOGLE: Can you restate</p> <p>24 the question for him or read back</p>	<p style="text-align: right;">Page 56</p> <p>1 of paper. So you're asking me, did I</p> <p>2 look at this a second time, a third time,</p> <p>3 the first time? I don't remember.</p> <p>4 Q. Do you remember asking for</p> <p>5 additional documents from plaintiffs'</p> <p>6 counsel after you served your first</p> <p>7 report?</p> <p>8 A. Yes, I do.</p> <p>9 Q. And the documents listed in</p> <p>10 Appendix A would be the documents that</p> <p>11 you requested, sir?</p> <p>12 A. Yes, it would be.</p> <p>13 Q. Now, you also reviewed</p> <p>14 documents from Cardinal, CVS and</p> <p>15 Walgreens that are listed in Appendix A;</p> <p>16 is that correct?</p> <p>17 A. I did.</p> <p>18 Q. And you had received those</p> <p>19 documents also after serving your first</p> <p>20 report?</p> <p>21 A. Yes, sir.</p> <p>22 Q. For the documents listed in</p> <p>23 Appendix A of your supplemental report,</p> <p>24 did you request those documents or did</p>
<p style="text-align: right;">Page 55</p> <p>1 or whatever?</p> <p>2 MR. EPPICH: I can restate</p> <p>3 it.</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. Dr. Whitelaw, did you review</p> <p>6 additional McKesson due diligence files</p> <p>7 in your May 10 supplemental report?</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: Yes, I did.</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. And when did you receive</p> <p>12 these documents from the plaintiffs'</p> <p>13 counsel?</p> <p>14 A. I can't really tell you when</p> <p>15 I received them, when I first received</p> <p>16 them from -- I'm sorry. I've looked at</p> <p>17 so many documents. I can't tell you</p> <p>18 specifically.</p> <p>19 Q. Was it after you served your</p> <p>20 April 15th report?</p> <p>21 A. I believe so.</p> <p>22 Q. You don't recall?</p> <p>23 A. I don't recall. As I said,</p> <p>24 I've looked at a lot of files and a lot</p>	<p style="text-align: right;">Page 57</p> <p>1 plaintiffs' counsel simply send them to</p> <p>2 you and ask you to look at those</p> <p>3 documents?</p> <p>4 MR. BOGLE: Are you</p> <p>5 referring to a specific section or</p> <p>6 just all of the documents, just so</p> <p>7 we're clear?</p> <p>8 BY MR. EPPICH:</p> <p>9 Q. Well, we could -- why don't</p> <p>10 we start with a broader question. All of</p> <p>11 the documents and we can narrow it down</p> <p>12 if we need to.</p> <p>13 MR. BOGLE: Okay.</p> <p>14 BY MR. RIVERA:</p> <p>15 Q. All right.</p> <p>16 A. Which documents in which</p> <p>17 section are we looking at please?</p> <p>18 Q. Well, I was thinking just of</p> <p>19 all the documents in Appendix A.</p> <p>20 A. Okay. All of the documents</p> <p>21 in Appendix A -- Appendix -- the</p> <p>22 documents in Sections A, B, and C, are</p> <p>23 all the things that I was looking at and</p> <p>24 there were things that I had found on my</p>

<p style="text-align: right;">Page 58</p> <p>1 own, so, they were not supplied.  2 In Section D, if that's  3 where you want to go, they were in  4 response to the ongoing continuing  5 requests for documents and new documents  6 that pertained to the sections, again,  7 from the eight elements of the federal  8 sentencing guidelines that pertained to  9 my framework.  10 So as new things became  11 available I looked at it. If it was  12 relevant to the report that I was writing  13 and the framework I was using, there was  14 an on -- you know, it was an ongoing  15 request for anything new, please let me  16 see it.  17 Q. Have you reviewed any  18 additional materials since your  19 supplemental report was served on  20 May 10th?  21 A. Not that I can recall.  22 Q. Have plaintiffs' counsel  23 sent -- has -- have plaintiffs' counsel  24 sent you any documents to review since</p>	<p style="text-align: right;">Page 60</p> <p>1 A. I do.  2 Q. You subsequently received an  3 LLM?  4 A. Yes, sir, I did.  5 Q. You also received a doctor  6 of judicial science, correct?  7 A. I received an SJD from  8 Widener University in health law, yes,  9 sir.  10 Q. And an SJD, I'm -- I'm not  11 familiar with it. Is that a doctor of  12 judicial science?  13 A. A doctorate of laws.  14 Q. Are you a member of the  15 Virginia and Pennsylvania bars?  16 A. I am.  17 Q. Do you maintain active --  18 active bar licenses in these two states?  19 A. I am inactive in Virginia.  20 I am active in Pennsylvania. But in good  21 standing in both.  22 Q. I would assume nothing less.  23 Let's look at Page 79.  24 A. You mean 279?</p>
<p style="text-align: right;">Page 59</p> <p>1 May 10th?  2 A. Again, not that I recall.  3 Q. Have you -- have you  4 reviewed the reports from any other  5 experts served in this litigation?  6 A. No, sir, I have not.  7 Q. And since you served your  8 supplemental report on May 10th, have  9 you -- have you reviewed any additional  10 deposition transcripts?  11 A. No, I don't believe I have.  12 Q. Mr. Whitelaw, let's take a  13 look at your CV which is in tab -- excuse  14 me, Exhibit 2 your first report. It  15 starts on Page 279.  16 A. Yes, sir.  17 Q. Is this an up-to-date  18 version of your CV?  19 A. Yeah, I believe it is.  20 Q. And to the best of your  21 knowledge, it's complete and accurate?  22 A. To the best of my knowledge  23 it is complete and accurate, sir.  24 Q. You hold a law degree?</p>	<p style="text-align: right;">Page 61</p> <p>1 Q. I'm sorry, Page 279. In  2 your professional summary.  3 A. Yes, sir.  4 Q. The second sentence in your  5 professional summary states, "His career  6 has focused on food and drug law and  7 corporate governance, as well as  8 designing and running compliance programs  9 within medical devices, pharmaceutical  10 sales and marketing, and pharmaceutical  11 R&amp;D."  12 Did I read that correctly?  13 A. Yes, I do believe you did.  14 Q. And this is an accurate  15 statement?  16 A. Yes, that is an accurate  17 statement.  18 Q. Let's look at the next  19 sentence in this paragraph. "He is a  20 licensed food and drug attorney, with a  21 doctorate in health law."  22 Those statement is also  23 accurate?  24 A. Yes.</p>

<p style="text-align: right;">Page 62</p> <p>1 Q. You are a licensed food and  2 drug attorney?  3 A. I practice my specialty is  4 food and drug.  5 Q. And you have a doctorate in  6 health law?  7 A. I do, from Widener  8 University as we just discussed.  9 Q. The next sentence reads,  10 "His forte is designing, building and  11 running life science compliance programs  12 from a 'blank sheet of paper.'"  13 Did I read that correctly?  14 A. You did.  15 Q. And is that statement  16 accurate?  17 A. Yeah, I think it's an  18 accurate statement.  19 Q. The statement does not  20 include the words wholesale  21 pharmaceutical distributors, correct?  22 A. No, sir, it does not.  23 Q. It does not include DEA  24 compliance programs, correct?</p>	<p style="text-align: right;">Page 64</p> <p>1 know, providing samples to, that they're  2 qualified to receive the samples, that  3 the inventories and samples that you  4 deliver are in fact given to sales reps,  5 are in fact -- are passed out to  6 healthcare providers, are in fact  7 accounted for. Any elements of diversion  8 on the other hand are then reported  9 appropriately to the appropriate  10 agencies, et cetera. So yes, I have done  11 that.  12 Q. Now, do sample and sample  13 capacity programs and PDMA compliance  14 programs, do -- do those -- do those  15 programs use 21 U.S.C. 823?  16 MR. BOGLE: Object to form.  17 You can answer if you understand.  18 THE WITNESS: I'm not sure I  19 understand the question that he's  20 asking.  21 BY MR. EPPICH:  22 Q. Well, do those programs, are  23 they governed by the Controlled  24 Substances Act and its affiliated</p>
<p style="text-align: right;">Page 63</p> <p>1 A. DEA compliance programs, as  2 we will -- as noted in my report, are a  3 subset of the larger corporate compliance  4 program.  5 So you have a corporate  6 compliance program. You have an  7 anti-diversion program under that. You  8 have a suspicious order monitoring  9 program under that.  10 So it's all sort of a  11 subsumed in the bigger picture. We are  12 talking compliance, we are talking  13 compliance with all laws and regulations,  14 the systems and processes designed at the  15 corporate level.  16 Q. Have you designed a DEA  17 compliance program before?  18 A. I have not designed a DEA  19 compliance program in the sense of a  20 controlled substances. I have designed a  21 sample and sample accountability PDMA  22 compliance programs. As you know, those  23 are substantially similar programs. You  24 need to know who you are selling -- you</p>	<p style="text-align: right;">Page 65</p> <p>1 regulations?  2 A. Only if you're dropping  3 samples under a -- only if you're  4 dropping controlled substances samples,  5 then yes, it would apply. If you're not  6 dropping controlled substances samples,  7 the answer is no, it would not apply.  8 Q. Do either of those programs  9 use suspicious order monitoring programs  10 as defined by the Controlled Substances  11 Act and its affiliated regulations?  12 A. Again, back to my original  13 answer, if you're dropping controlled  14 substances samples, you would need to  15 comply with the suspicious order  16 monitoring requirements, as well as the  17 PDMA requirements. And if you're  18 dropping non controlled substances, then  19 the answer would be you do not need to  20 comply.  21 Q. And did -- did any of the  22 programs that you designed drop sample --  23 controlled substances into them?  24 A. Not that --</p>

<p style="text-align: right;">Page 66</p> <p>1 MR. BOGLE: Object to form.          2 Go ahead.          3 THE WITNESS: That I          4 designed, no. Although I was          5 working on a program for -- when I          6 was at Deloitte, we were working          7 on a program at the request of          8 Henry Schein. We were bidding on          9 an opportunity. And we were going          10 to be -- and we were laying out          11 how we designed our -- how you          12 would design that program, so. So          13 to that extent, yes.          14 BY MR. EPPICH:          15 Q. Did you win that business          16 for Henry Schein?          17 A. No. Unfortunately we          18 didn't. My understanding from the          19 feedback I got from the partner, it was a          20 price point issue.          21 Q. When was the first time that          22 you read 21 U.S.C. 823?          23 A. Holy cow. I've been doing          24 this 30 years. I can't tell you. But it</p>	<p style="text-align: right;">Page 68</p> <p>1 firm is even still in existence at this          2 point.          3 Q. Your work at the Fox Bennett          4 &amp; Turner firm was on food, drug, and          5 environmental issues, correct?          6 A. Correct.          7 Q. After a year at Fox          8 Bennett &amp; Turner, you moved to the          9 company of FD Inc.?          10 A. Mm-hmm.          11 Q. And you were the head of          12 sales and marketing?          13 A. I did.          14 MR. BOGLE: Make sure you          15 say yes or no rather than          16 "mm-hmm," just sort of -- so the          17 record is clear. The court          18 reporter will get onto you a          19 little.          20 THE WITNESS: Thank you.          21 MR. BOGLE: She's nice,          22 but...          23 THE WITNESS: I'll try to do          24 better.</p>
<p style="text-align: right;">Page 67</p> <p>1 would have been a long time ago. First          2 time I read it? A long time ago.          3 Q. You worked as an intern at          4 the office of chief counsel at FDA?          5 A. I did for a period of time.          6 Q. It was for one year,          7 correct?          8 A. Correct.          9 Q. That was from 1988 to 1989?          10 A. That is correct.          11 Q. And then you took an          12 associate position at Fox Bennett &amp;          13 Turner?          14 A. Mm-hmm.          15 Q. That was your first position          16 after law school, right?          17 A. Yeah. That would have been          18 correct.          19 Q. And Fox Bennett &amp; Turner is          20 a private law firm?          21 A. Yes. Was originally Fox          22 Weinberg &amp; Bennett. Is now -- it was          23 then Fox Bennett &amp; Turner. I have no          24 idea what it's evolved into now, If the</p>	<p style="text-align: right;">Page 69</p> <p>1 MR. BOGLE: You're fine.          2 BY MR. EPPICH:          3 Q. You're doing fine. So at FD          4 Incorporated, you were the head of sales          5 and marketing, correct?          6 A. I was.          7 Q. You were focused on          8 marketing strategies in this position?          9 A. Yes, actually, I was.          10 Q. For food and drug statutory          11 administrative and regulatory materials,          12 correct?          13 A. Correct.          14 Q. Now, after the FD company,          15 you became the senior attorney and          16 compliance coordinator at C.R. Bard; is          17 that right?          18 A. Yes, sir, I did.          19 Q. C.R. Bard is a medical          20 device manufacturer?          21 A. Yes.          22 Q. C.R. Bard manufactures          23 medical devices such as stents,          24 catheters, surgical mesh; is that true?</p>



<p style="text-align: right;">Page 70</p> <p>1 A. Never -- my time, never  2 manufactured stents. Surgical catheters,  3 yes. Feeding tubes, yes. Urological  4 catheters, yes. Other specialty  5 catheters, yes. And electrophysiology  6 devices. It was a whole host of devices.  7 Q. C.R. Bard is not a wholesale  8 drug distributor, is it?  9 A. Not by the definition of  10 what a wholesale drug distributor is, no.  11 Q. C.R. Bard does not  12 manufacture opioids?  13 A. At least not when I was  14 there, no they did not.  15 Q. C.R. Bard does not  16 distribute opioids?  17 A. Not when -- during the time  18 that I was present.  19 Q. Or any other controlled  20 substance?  21 A. To the best of my knowledge,  22 again, not when I was there.  23 Q. Did you provide any  24 compliance advice regarding the</p>	<p style="text-align: right;">Page 72</p> <p>1 created and implemented policies to  2 reduce the risk from perceived improper  3 influence with healthcare professionals;  4 is that right?  5 A. That's part of what I did,  6 yes.  7 Q. Those policies are  8 anti-kickback measures, right?  9 A. They are not only  10 anti-kickback measures. Again, as we  11 discussed earlier, I did PDMA work for  12 them as well and sample accountability  13 work as well. They're not only  14 anti-kickback statutes. There's false  15 claims work.  16 Q. How much of your time was --  17 how much of your work at SmithKline  18 related to PDMA's and sample -- and sample  19 programs?  20 A. Honestly, I spent at least a  21 quarter of my time, if not more, on that.  22 We had lots of investigations. We had  23 lots of issues. We were putting in new  24 systems, controls, writing new policies.</p>
<p style="text-align: right;">Page 71</p> <p>1 Controlled Substances Act in your  2 position at C.R. Bard?  3 A. I may have. I don't recall.  4 You're asking me -- you're asking me  5 something 30 years ago, so entirely  6 possible. We used -- we had  7 laboratories. We used controlled  8 substances in those laboratories to the  9 best of my recollection. And is there a  10 chance I said something at some point on  11 it, yes. Do I rightly remember, no, sir  12 I don't.  13 Q. Did you provide any  14 compliance advice relating to a  15 suspicious order monitoring program while  16 at C.R. Bard?  17 A. That I can say we did not  18 have.  19 Q. After C.R. Bard, you became  20 the legal compliance officer at  21 SmithKline Beecham Pharmaceuticals?  22 A. Beecham. Yes.  23 Q. Beecham, thank you.  24 And your CV says that you</p>	<p style="text-align: right;">Page 73</p> <p>1 It was a substantial chunk of time.  2 Q. And these policies, these  3 PDMA sample and sample policies that  4 you've mentioned a few times, they focus  5 on policies that govern providing samples  6 that are given to physicians, right?  7 A. Correct. But we're -- but  8 let's be clear. The kinds of controls  9 that you're putting in around PDMA,  10 non-controlled substances samples are  11 substantially equivalent to what you're  12 doing in controlled substances work.  13 You need to know the right  14 people that you're dropping to. You need  15 to account for your inventory. You need  16 to look for suspicious behavior. You  17 need to report suspicious behavior. You  18 need to investigate red flags. You need  19 to investigate noncompliance. You need  20 to report noncompliance.  21 It's all, again, pretty much  22 substantially similar to the world of  23 controlled substances. You're just  24 working with a different set of products.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. But the policies focus on  2 providing samples to physicians, that's  3 true, correct?  4 A. That -- that is true.  5 Q. Now, SmithKline was --  6 A. Or other -- other  7 prescribers, so let's be clear. You can  8 have nurse practitioners, or physician's  9 assistants, who also have prescribing  10 privileges. We could provide samples to  11 them.  12 Q. Thank you for that.  13 SmithKline was a  14 pharmaceutical manufacturer, right?  15 A. That is correct.  16 Q. SmithKline was not a  17 wholesale drug distributor?  18 A. No, sir, it was not.  19 Q. SmithKline did not  20 manufacture opioids, correct?  21 A. No.  22 Q. SmithKline did not  23 distribute opioids?  24 A. To the best of my knowledge,</p>	<p style="text-align: right;">Page 76</p> <p>1 requirements?  2 A. Domestic and international,  3 yes.  4 Q. Now, GlaxoSmithKline is a  5 pharmaceutical manufacturer, correct?  6 A. Yes, sir, it is.  7 Q. GlaxoSmithKline is not a  8 wholesale drug distributor?  9 A. That is correct.  10 Q. GlaxoSmithKline does not  11 manufacture opioids?  12 A. No. GlaxoSmithKline does  13 not manufacture opioids. But let us be  14 clear, and especially in the research and  15 development arm, they use opioids.  16 Opioids are used in the testing. So,  17 therefore, DEA compliance such as  18 security controls, vaults, sign-ins, all  19 that is absolutely relevant. And yes, I  20 did work in that space.  21 Q. But -- and I appreciate that  22 distinction. But GlaxoSmithKline does  23 not manufacture opioids, correct?  24 A. That is correct.</p>
<p style="text-align: right;">Page 75</p> <p>1 no. I don't believe we had any products  2 that were opioids.  3 Q. And SmithKline did not  4 distribute controlled substances?  5 A. Again, to the best of my  6 recollection, we did not distribute any  7 controlled substances.  8 Q. Now, you were promoted -- or  9 excuse me. Let me strike that.  10 At some point SmithKline  11 merged with Glaxo, correct?  12 A. That is correct.  13 Q. And you became the  14 compliance officer?  15 A. I became the compliance  16 officer for the global R&amp;D business unit.  17 Q. You ensured that Glaxo --  18 and the new company was known as  19 GlaxoSmithKline?  20 A. That's correct.  21 Q. And you ensured in your  22 position that GlaxoSmithKline's global  23 research and development operations  24 complied with international regulatory</p>	<p style="text-align: right;">Page 77</p> <p>1 Q. GlaxoSmithKline does not  2 distribute opioids, correct?  3 A. Correct.  4 Q. GlaxoSmithKline does not  5 distribute controlled substances?  6 A. That is correct.  7 Q. After GlaxoSmithKline, you  8 became a director in the life sciences  9 compliance department at Deloitte &amp;  10 Touche?  11 A. I did.  12 Q. Your LinkedIn page states  13 that you had a special focus on bribery  14 and corruption issues pertaining to  15 research trials, and grants, medical  16 affairs and medical science liaisons?  17 A. That was certainly one of  18 the focuses. But I had -- again, my  19 duties as a director of life sciences  20 buttoned up around a bunch -- bunch of  21 duties.  22 But, yes, my specialty was  23 that particular area. I had a lot of  24 expertise in that space.</p>

<p style="text-align: right;">Page 78</p> <p>1 Q. And turning back to your CV  2 that's attached to your report. It says  3 "During your time at Deloitte &amp; Touche,  4 you led the advisory practice" -- pardon,  5 you were the lead -- I'm going to strike  6 that.  7 When -- when you were --  8 when you were at Deloitte &amp; Touche you  9 led the advisory practices transparency  10 team to advise clients on compliance with  11 the Sunshine Act and its international  12 equivalence?  13 A. Yes, I did.  14 Q. Now, the Sunshine Act is  15 governed by the centers for Medicare and  16 Medicaid services?  17 A. Here in the United States,  18 yes. It's also -- but the controlling  19 statute is the Affordable Care Act.  20 Q. You did not provide any  21 compliance advice to wholesale  22 distributors while at Deloitte, correct?  23 A. We had that discussion. And  24 the answer was we were working, trying to</p>	<p style="text-align: right;">Page 80</p> <p>1 let me be clear --  2 A. I can't give you any more  3 other than -- other than, yeah, they were  4 clients of ours, and, yes, if they needed  5 compliance advice or --  6 Q. Let me -- let me just ask  7 you --  8 MR. BOGLE: Hold on, hold  9 on, hold on. Are you finished  10 with your answer?  11 THE WITNESS: Yeah.  12 MR. BOGLE: Okay.  13 MR. EPPICH: I was just  14 trying to stop him, because I -- I  15 don't want to get into any  16 confidential information --  17 MR. BOGLE: Yeah, I don't  18 want you to either.  19 THE WITNESS: I'm not going  20 to get you there.  21 BY MR. EPPICH:  22 Q. Sir, I just -- I'm just -- I  23 just want to know generally, did you  24 provide any guidance to any wholesale</p>
<p style="text-align: right;">Page 79</p> <p>1 work with, for example, with Henry Schein  2 and it did not come to fruition. But did  3 I -- if the project had come to fruition,  4 I was the lead director on that project,  5 and yes, we would have.  6 Q. But other than your pitch  7 for Henry Schein that did not come about,  8 you did not provide any compliance advice  9 to wholesale distributors at your job at  10 Deloitte?  11 MR. BOGLE: Object to form.  12 THE WITNESS: I'm pausing,  13 Chris, because we -- I did work on  14 and off with other wholesale  15 distributors on other issues. I  16 was brought in with ABC, I think  17 at some point to advise on  18 anti-kickback and FCA.  19 But again, you're asking me  20 for conversations with other  21 partners.  22 BY MR. EPPICH:  23 Q. I'm not interested in any  24 confidential information. Just let me --</p>	<p style="text-align: right;">Page 81</p> <p>1 distributor on the topic of suspicious  2 order monitoring programs while you  3 worked at Deloitte.  4 A. Other than the topic we  5 discussed previously, no.  6 Q. And that topic is the Henry  7 Schein?  8 A. Henry Schein.  9 Q. Thank you.  10 Did you provide any  11 compliance advice to opioid manufacturers  12 during your time at Deloitte?  13 A. Yes. I did provide  14 compliance advice.  15 Q. And did you provide any  16 compliance advice -- and I'm just asking  17 for generally --  18 A. I know.  19 Q. -- on the -- on suspicious  20 order monitoring programs?  21 A. Not that topic, per se, but  22 other topics.  23 Q. After Deloitte you moved to  24 a company named Misonix?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. Misonix.</p> <p>2 Q. Misonix. I butchered that</p> <p>3 one, didn't I?</p> <p>4 You became the interim chief</p> <p>5 compliance officer at Misonix?</p> <p>6 A. I was interim chief</p> <p>7 compliance officer.</p> <p>8 Q. You were there for about</p> <p>9 seven months?</p> <p>10 A. Yes.</p> <p>11 Q. And why -- why did you leave</p> <p>12 after seven months?</p> <p>13 A. Because they no longer</p> <p>14 needed the services that I was providing.</p> <p>15 My job was to stand up and get the</p> <p>16 compliance program running for that -- it</p> <p>17 was a small company.</p> <p>18 Q. It was a medical device</p> <p>19 company?</p> <p>20 A. Medical device company on</p> <p>21 Long Island.</p> <p>22 Q. Misonix is not a wholesale</p> <p>23 pharmaceutical distributor?</p> <p>24 A. No, sir.</p>	<p style="text-align: right;">Page 84</p> <p>1 medium-sized FDA regulatory companies?</p> <p>2 A. I do focus on them.</p> <p>3 Q. Your company does not focus</p> <p>4 on compliance at large companies,</p> <p>5 correct?</p> <p>6 MR. BOGLE: Object to form.</p> <p>7 THE WITNESS: Typically,</p> <p>8 Chris, it doesn't, although I will</p> <p>9 do work for large companies.</p> <p>10 Typically the larger companies are</p> <p>11 looking for the Deloitte &amp;</p> <p>12 Touches, the Pfizers. And the</p> <p>13 Pfizers of the world, GSKs of the</p> <p>14 world are looking for the large</p> <p>15 big four. I'm not trying to</p> <p>16 compete with the big four. That's</p> <p>17 not the services that I provide.</p> <p>18 BY MR. EPPICH:</p> <p>19 Q. I was looking at your</p> <p>20 company's website, specifically the</p> <p>21 advertised services that you advertise.</p> <p>22 And I saw that you -- you do not</p> <p>23 advertise services for pharmaceutical</p> <p>24 wholesale distributors, correct?</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Misonix does not manufacture</p> <p>2 opioids?</p> <p>3 A. No.</p> <p>4 Q. Misonix does not manufacture</p> <p>5 controlled substances, correct?</p> <p>6 A. No, sir, it does not.</p> <p>7 Q. Following your time at</p> <p>8 Misonix, you started the Whitelaw</p> <p>9 Compliance Group?</p> <p>10 A. No, actually the Whitelaw</p> <p>11 Compliance Group predates my job -- my</p> <p>12 job at Misonix. And Misonix was part</p> <p>13 of -- was a consulting gig.</p> <p>14 Q. Your current position is the</p> <p>15 president and CEO of Whitelaw Compliance</p> <p>16 Group, correct?</p> <p>17 A. Correct. It's my company.</p> <p>18 Q. Your company is described in</p> <p>19 your CV, as, "Focused exclusively to</p> <p>20 small to medium-sized FDA-regulated</p> <p>21 companies." Is that right?</p> <p>22 A. That's -- that's the general</p> <p>23 direction that I work in, yes.</p> <p>24 Q. You focus on small and</p>	<p style="text-align: right;">Page 85</p> <p>1 A. No, I don't. I haven't.</p> <p>2 Q. You don't advertise services</p> <p>3 for chain pharmacies, do you?</p> <p>4 A. No. I have not explored</p> <p>5 either of those two marketing segments,</p> <p>6 although I have thought about expanding</p> <p>7 into it. But again you're talking to a</p> <p>8 gentleman who runs his own firm, who does</p> <p>9 both sales and delivery on the work that</p> <p>10 I do. So there's -- there's so much.</p> <p>11 But would I do work for a wholesaler?</p> <p>12 Yes. Could I do work for a wholesaler?</p> <p>13 Yes. Could I do work for a chain</p> <p>14 pharmacy? Absolutely.</p> <p>15 Q. You also don't list</p> <p>16 experiences or services concerning the</p> <p>17 Controlled Substances Act on your</p> <p>18 website, do you?</p> <p>19 A. I highlight the main areas</p> <p>20 that I focus on. I don't highlight every</p> <p>21 area that I focus on. And controlled</p> <p>22 substances is not an area that is listed,</p> <p>23 if that's what you're asking.</p> <p>24 Q. You don't list any of your</p>

Page 86

1 experiences or services concerning DEA on  
2 your website, do you?  
3 A. Not that I rightly recall.  
4 Q. Mr. Whitelaw, you never  
5 worked at the DEA, did you?  
6 A. No, sir. I didn't. I  
7 didn't have the honor.  
8 Q. You've never worked at a  
9 wholesale distributor?  
10 A. No.  
11 Q. Do you know how many  
12 wholesale distributors are in the United  
13 States right now?  
14 A. No. Afraid I don't have a  
15 hard count for you.  
16 Q. And you testified earlier  
17 that you've never designed a compliance  
18 program for wholesale distributor that's  
19 currently in use, correct?  
20 A. No. That's not what I  
21 testified to. You asked me if I did  
22 controlled substances work. As far as  
23 designing compliance programs for others,  
24 yes, I have.

Page 87

1 Q. Let me ask it a different  
2 way then. Have you designed a compliance  
3 program for a pharmaceutical wholesale  
4 distributor that is currently in use at  
5 that distributor?  
6 MR. BOGLE: Object to form.  
7 THE WITNESS: I have no way  
8 of knowing if the work that I did  
9 is still being used. So I can't  
10 answer the question for you. I'm  
11 sorry.  
12 BY MR. EPPICH:  
13 Q. Which compliance program are  
14 you thinking of that you don't know if it  
15 is or is not currently in use?  
16 A. You're asking me -- it would  
17 have to be naming client names.  
18 MR. BOGLE: Yeah, I mean, if  
19 you've got any confidentiality  
20 issues --  
21 THE WITNESS: I've got  
22 confidentiality issues on this.  
23 BY MR. EPPICH:  
24 Q. Is this compliance program

Page 88

1 at any of the defendants named in this  
2 litigation?  
3 A. Yes.  
4 Q. Have you ever worked at a  
5 chain pharmacy?  
6 A. No, sir.  
7 Q. Have you ever designed a  
8 compliance program for a large chain  
9 pharmacy that is currently in use?  
10 A. No, sir.  
11 Q. Have you ever designed a  
12 controlled substance compliance program  
13 for a pharmaceutical manufacturer that is  
14 currently in use?  
15 MR. BOGLE: Object to form.  
16 THE WITNESS: Again, I can't  
17 answer that for you. I don't  
18 know.  
19 BY MR. EPPICH:  
20 Q. On your CV, I notice that  
21 your CV does not mention the Controlled  
22 Substances Act; is that true? Would you  
23 agree?  
24 A. I would have to read it all

Page 89

1 over again. Do you want to give me a  
2 minute to read it to make sure that I can  
3 answer that honestly?  
4 MR. BOGLE: If you need to  
5 read it, you can read it.  
6 THE WITNESS: No, it doesn't  
7 say the magic word "controlled  
8 substances" in my resumé.  
9 BY MR. EPPICH:  
10 Q. Your CV doesn't mention  
11 opioids, does it?  
12 A. No, it doesn't have that  
13 magic word in there either.  
14 Q. And it doesn't mention  
15 controlled substances?  
16 A. I believe I just answered  
17 that question, and the answer is no, it  
18 does not.  
19 Q. Your CV doesn't mention  
20 diversion of opioids at all either, does  
21 it?  
22 A. No, sir, it does not.  
23 Q. The DEA and the FDA, you're  
24 familiar with those agencies?



<p style="text-align: right;">Page 90</p> <p>1 A. DEA and FDA?</p> <p>2 Q. Yes, sir.</p> <p>3 A. Yes, sir, I'm familiar with</p> <p>4 both agencies.</p> <p>5 Q. And the DEA and the FDA are</p> <p>6 different federal agencies, correct?</p> <p>7 A. Yes, that is correct.</p> <p>8 Q. DEA and FDA have different</p> <p>9 regulatory focuses?</p> <p>10 MR. BOGLE: Object to form.</p> <p>11 THE WITNESS: So they have</p> <p>12 different regulatory focuses, but</p> <p>13 I would also qualify that there's</p> <p>14 overlap between the two, and the</p> <p>15 two work together in certain</p> <p>16 instances, controlled substances</p> <p>17 being an excellent example of</p> <p>18 that.</p> <p>19 BY MR. EPPICH:</p> <p>20 Q. Well, the DEA is the agency</p> <p>21 with primary responsibility for enforcing</p> <p>22 the Controlled Substances Act, correct?</p> <p>23 A. With the Controlled</p> <p>24 Substances Act, yes.</p>	<p style="text-align: right;">Page 92</p> <p>1 questions, and then we'll be at a</p> <p>2 good break.</p> <p>3 MR. BOGLE: That's fine.</p> <p>4 That's fine.</p> <p>5 BY MR. EPPICH:</p> <p>6 Q. I just want to finish up</p> <p>7 your resumé, sir.</p> <p>8 MR. BOGLE: That's fine.</p> <p>9 BY MR. EPPICH:</p> <p>10 Q. You teach as a senior fellow</p> <p>11 and adjunct professor in life sciences</p> <p>12 compliance at the Mitchell Hamline School</p> <p>13 of Law in St. Paul, Minnesota, correct?</p> <p>14 A. Yes, sir, I do.</p> <p>15 Q. You currently teach there?</p> <p>16 A. Yes, sir, I do. In fact I'm</p> <p>17 grading final exams as we speak.</p> <p>18 Q. Do you live in Philadelphia</p> <p>19 or do you live in St. Paul?</p> <p>20 A. I live in Philadelphia, sir.</p> <p>21 Q. Have you ever taught a class</p> <p>22 on the Controlled Substances Act?</p> <p>23 MR. BOGLE: Object to form.</p> <p>24 THE WITNESS: No, not</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. And the FDA is not the</p> <p>2 government agency charged with enforcing</p> <p>3 the Controlled Substances Act, correct?</p> <p>4 A. That is --</p> <p>5 MR. BOGLE: Object to form.</p> <p>6 THE WITNESS: That is</p> <p>7 correct.</p> <p>8 BY MR. EPPICH:</p> <p>9 Q. FDA does not promulgate</p> <p>10 regulations under the Controlled</p> <p>11 Substances Act?</p> <p>12 A. I'm sorry. Say that again,</p> <p>13 please.</p> <p>14 Q. Does the FDA promulgate</p> <p>15 regulations under the Controlled</p> <p>16 Substances Act?</p> <p>17 A. Not usually.</p> <p>18 Q. Not ever, correct?</p> <p>19 A. To the best of my knowledge,</p> <p>20 no.</p> <p>21 MR. BOGLE: Chris, if you're</p> <p>22 shifting to another area, we've</p> <p>23 been almost an hour ten I think.</p> <p>24 MR. EPPICH: Maybe ten more</p>	<p style="text-align: right;">Page 93</p> <p>1 directly.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. Have you ever taught a law</p> <p>4 school class on DEA compliance?</p> <p>5 A. Not with its sole focus</p> <p>6 being DEA compliance, no.</p> <p>7 Q. Let me just ask you a quick</p> <p>8 question about Page 283 of your -- of</p> <p>9 your publications on your CV.</p> <p>10 A. Sure, just one second. I'm</p> <p>11 there.</p> <p>12 Q. Pages 283 to, I think, 286,</p> <p>13 is this a complete list of your</p> <p>14 publications, sir?</p> <p>15 A. To the best of my knowledge,</p> <p>16 sir, it is. I've written a lot over</p> <p>17 30 years. I try to be as complete and</p> <p>18 thorough as possible.</p> <p>19 Q. Have you ever published an</p> <p>20 article on DEA compliance?</p> <p>21 A. Not that I can -- when you</p> <p>22 say did I ever publish, yes, in my</p> <p>23 capacity working as an editor,</p> <p>24 absolutely. Have I actually -- I mean,</p>

<p style="text-align: right;">Page 94</p> <p>1 is that the question?</p> <p>2 Q. Have -- well, we'll take</p> <p>3 them one at a time. Have you ever</p> <p>4 written an article on DEA compliance?</p> <p>5 A. I have to read through the</p> <p>6 entire list to be absolutely sure.</p> <p>7 But --</p> <p>8 MR. BOGLE: If you need to</p> <p>9 look you can look.</p> <p>10 THE WITNESS: The answer to</p> <p>11 your question is no. No, sir.</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. Now, shifting to your</p> <p>14 publication, your -- your work as an</p> <p>15 editor --</p> <p>16 A. Yeah.</p> <p>17 Q. -- have you ever published</p> <p>18 an article on a compliance program for a</p> <p>19 wholesale pharmaceutical distributor?</p> <p>20 A. No.</p> <p>21 Q. Have you ever published an</p> <p>22 article on DEA compliance for a</p> <p>23 manufacturer?</p> <p>24 A. We've published articles in</p>	<p style="text-align: right;">Page 96</p> <p>1 statement, sir.</p> <p>2 Q. You then state you created</p> <p>3 and implemented Bard's original medical</p> <p>4 device compliance program to meet the</p> <p>5 requirements of the federal sentencing</p> <p>6 guidelines and Bard's plea agreement with</p> <p>7 the U.S. Department of Justice, and</p> <p>8 served as Bard's first compliance officer</p> <p>9 post-settlement.</p> <p>10 Is that -- is that accurate?</p> <p>11 A. That is all accurate, sir.</p> <p>12 Q. So you oversaw the design</p> <p>13 and implementation of C.R. Bard's medical</p> <p>14 device compliance program, is that true?</p> <p>15 A. I oversaw the implementation</p> <p>16 and design of their corporate compliance</p> <p>17 program, yes.</p> <p>18 Q. And their -- their corporate</p> <p>19 compliance program was directed at</p> <p>20 medical devices, correct?</p> <p>21 A. Their business was in</p> <p>22 medical devices, yes.</p> <p>23 Q. When you designed C.R.</p> <p>24 Bard's medical compliance program, you</p>
<p style="text-align: right;">Page 95</p> <p>1 general on DEA compliance. On a specific</p> <p>2 compliance program and the elements</p> <p>3 necessary for a manufacturer, no, sir.</p> <p>4 MR. EPPICH: Let's go ahead</p> <p>5 and take a break. Let's go off</p> <p>6 the record.</p> <p>7 THE VIDEOGRAPHER: Going off</p> <p>8 the record, 10:26 a.m.</p> <p>9 (Short break.)</p> <p>10 THE VIDEOGRAPHER: We are</p> <p>11 back on the record at 10:44 a.m.</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. All right, Dr. Whitelaw, I</p> <p>14 want to ask you a few more questions</p> <p>15 about your work at C.R. Bard. And this</p> <p>16 is -- we are back on Page 281 of your</p> <p>17 report.</p> <p>18 A. Okay. Yes, of course. I'm</p> <p>19 here.</p> <p>20 Q. Now, it says -- it says that</p> <p>21 you served as Bard's first compliance</p> <p>22 officer, post-settlement.</p> <p>23 Is that accurate?</p> <p>24 A. Yes, that's an accurate</p>	<p style="text-align: right;">Page 97</p> <p>1 designed the program to comply -- comply</p> <p>2 with existing laws and regulations?</p> <p>3 A. Yes.</p> <p>4 Q. When you designed C.R.</p> <p>5 Bard's compliance program, you relied on</p> <p>6 the guidance from the relevant regulatory</p> <p>7 agencies available at the time, correct?</p> <p>8 A. Well, that's part of what I</p> <p>9 relied on. I relied on an awful lot</p> <p>10 more. I also relied on the experience,</p> <p>11 again, this would have been preguidance</p> <p>12 from OIG and preguidance from department</p> <p>13 of justice in this space, so the only</p> <p>14 ones that had any real guidance were the</p> <p>15 defense industry at the time. So there</p> <p>16 were a lot of conversations I had with</p> <p>17 the folks at Boeing and other places to</p> <p>18 understand what they had gone through</p> <p>19 from a defense contracting compliance</p> <p>20 program perspective.</p> <p>21 See, you have to remember</p> <p>22 this is the day when there was very</p> <p>23 little out there. This was new to the</p> <p>24 life sciences industry as a whole and the</p>

<p style="text-align: right;">Page 98</p> <p>1 first time they had experiences with it. 2 So we had to look to other industries for 3 guidance and support and information 4 and -- but it was a wide ranging bit of 5 work that had to be done. 6 Q. So designing this program, 7 you went out and sought all the guidance 8 that you could from the relevant folks 9 with information and you applied that 10 information that was available at -- at 11 that time in designing Bard's compliance 12 program? 13 A. Correct. Mm-hmm. 14 Q. Now, was there any guidance 15 available from FDI -- let me strike that. 16 Was there any guidance 17 available from FDA at that time? 18 MR. BOGLE: Object to form. 19 Vague and ambiguous. 20 THE WITNESS: Could you be 21 more specific when you say type of 22 guidance? Because obviously the 23 Food and Drug Administration puts 24 out lots and lots of guidance,</p>	<p style="text-align: right;">Page 100</p> <p>1 BY MR. EPPICH: 2 Q. I think you actually 3 answered my question. 4 So let me ask you a 5 different question. 6 You'd agree that it's 7 appropriate for a regulated company like 8 C.R. Bard to rely on the available 9 guidance from the relevant regulatory 10 agency in the design of its compliance 11 programs? 12 A. I believe that is one thing 13 to rely on. I believe it's one thing to 14 use, is the relevant guidance that's 15 available, yes. But obviously it's 16 guidance and guidance obviously has to be 17 tailored. One of the keys to any -- a 18 good compliance program, as I emphasize 19 throughout the report is, you have to 20 tailor for the individual company, and 21 individual practices, and individual 22 structure. It's a unique entity. 23 So while the framework and 24 the elements are all the same, and you</p>
<p style="text-align: right;">Page 99</p> <p>1 lots and lots of guidance around 2 medical devices too. 3 BY MR. EPPICH: 4 Q. That's fair. 5 A. I'm not sure I know what 6 you -- 7 Q. Did -- did DEA provide any 8 guidance that was relevant to the design 9 of C.R. Bard's compliance program that 10 was available at the time? 11 MR. BOGLE: Object to form. 12 THE WITNESS: Again, as I 13 said, I mean -- I mean, pick a 14 topic and we can find something 15 where there's relevant guidance. 16 How do you write a 510(k). 17 When do you need to file a 510(k). 18 When do you need to do a clinical 19 trial. How do you do a clinical 20 trial. When do you have to file 21 an IDE. 22 I'm -- I'm honestly, Chris, 23 not sure what you're asking me. 24 Can you be more specific, please?</p>	<p style="text-align: right;">Page 101</p> <p>1 use the same elements, you use the same 2 elements over and over, the eight 3 elements that we talked about at the 4 beginning of this. It has to be adapted 5 and tailored to your -- to the individual 6 company, in order to be deemed and 7 actually be effective. 8 Q. So when you design C.R. 9 Bard's compliance program, you relied on 10 all of the information, all of this 11 information that you -- 12 A. I gathered as much -- 13 MR. BOGLE: Wait until he 14 finishes. 15 BY MR. EPPICH: 16 Q. -- that was available to you 17 at the time, correct? 18 MR. BOGLE: Object to form. 19 THE WITNESS: I gathered as 20 much information as I could to 21 inform my decisions, yes. 22 BY MR. EPPICH: 23 Q. You held this position at 24 C.R. Bard for about six years; is that</p>

<p style="text-align: right;">Page 102</p> <p>1 correct?</p> <p>2 A. That would be about right,</p> <p>3 yeah.</p> <p>4 Q. And over that time, you'd</p> <p>5 agree that technology changed, correct?</p> <p>6 MR. BOGLE: Object to form.</p> <p>7 Vague and ambiguous.</p> <p>8 THE WITNESS: When you say</p> <p>9 technology, what do you mean?</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. Computers got better.</p> <p>12 Communication capabilities improved.</p> <p>13 Technology improved.</p> <p>14 A. Technology did change, yes.</p> <p>15 Q. And you'd expect a</p> <p>16 compliance program to change over time to</p> <p>17 incorporate these changes to technology</p> <p>18 as it became available, wouldn't you?</p> <p>19 A. I would expect them to take</p> <p>20 it into account. Whether they would</p> <p>21 actually adopt it and incorporate and use</p> <p>22 it, again depends on the individual needs</p> <p>23 of the individual company.</p> <p>24 I mean, if we -- if we go</p>	<p style="text-align: right;">Page 104</p> <p>1 incorporate it. Not necessarily.</p> <p>2 Again it depends on facts --</p> <p>3 it depends on facts and circumstances,</p> <p>4 the nature of the client, how they're</p> <p>5 structured, how they're organized. How</p> <p>6 many people are involved, how many sites</p> <p>7 are involved. I mean, there are a whole</p> <p>8 range of elements you can go down and</p> <p>9 look at when we're evaluating whether</p> <p>10 technology is a good fit or not.</p> <p>11 Q. And while you were at C.R.</p> <p>12 Bard, did the C.R. Bard compliance</p> <p>13 program incorporate or adopt -- change to</p> <p>14 incorporate or adopt new technology?</p> <p>15 MR. BOGLE: Object to form.</p> <p>16 Vague and ambiguous.</p> <p>17 THE WITNESS: Is there a</p> <p>18 particular area you wish to talk</p> <p>19 about or -- I mean, again, we had</p> <p>20 better e-mail systems and e-mail</p> <p>21 servers, had a better laptop. I'm</p> <p>22 not sure -- I'm not sure if you're</p> <p>23 asking -- what you're asking in</p> <p>24 particular.</p>
<p style="text-align: right;">Page 103</p> <p>1 back for example and take a look at</p> <p>2 Misonix, if you have a 20-person,</p> <p>3 40-person company, everybody is down the</p> <p>4 hall from everybody else. You might not</p> <p>5 need, you know, a very large or</p> <p>6 complicated learning management system.</p> <p>7 You might be able to do it with just</p> <p>8 paper records, which is what they did.</p> <p>9 So it has to be adapted to</p> <p>10 the -- to the actual client.</p> <p>11 Q. But you'd agree with me that</p> <p>12 if the technology was useful for</p> <p>13 improving the compliance program that</p> <p>14 you'd expect the compliance program to</p> <p>15 change to adopt that new and useful</p> <p>16 technology?</p> <p>17 A. I think where I was going</p> <p>18 before was the same place I am now, which</p> <p>19 is you need to evaluate it. And if it's</p> <p>20 useful and effective and all the other</p> <p>21 attributes you go to, incorporate what's</p> <p>22 good, and don't incorporate what doesn't</p> <p>23 work. But it's not an automatic just</p> <p>24 because technology changes, do you</p>	<p style="text-align: right;">Page 105</p> <p>1 BY MR. EPPICH:</p> <p>2 Q. For example, perhaps you</p> <p>3 used -- when you -- when you started the</p> <p>4 design of C.R. Bard compliance program in</p> <p>5 2001, I believe it was, right?</p> <p>6 A. No. I started with Bard</p> <p>7 long before that. I started with Bard in</p> <p>8 1991. I started working on the</p> <p>9 compliance program in 1993.</p> <p>10 Q. Thank you. Thank you for</p> <p>11 that. So when you started to work on the</p> <p>12 compliance program in 1993, this is when</p> <p>13 Windows 95, Microsoft Windows 95, was not</p> <p>14 available, correct?</p> <p>15 A. I honestly don't remember</p> <p>16 what we were working off of at the time.</p> <p>17 I do remember -- seem to recall we were</p> <p>18 working off of -- I think we were working</p> <p>19 off of Lotus e-mail.</p> <p>20 Q. You were working off of</p> <p>21 Lotus e-mail? When you left C.R. Bard in</p> <p>22 '97, was C.R. Bard's compliance program</p> <p>23 still using Lotus?</p> <p>24 A. Actually, I believe we were.</p>

<p style="text-align: right;">Page 106</p> <p>1 I think we were using at that point it                  2 had become the iteration called Lotus                  3 Notes.                  4 But I honestly -- it's so                  5 long ago, I don't remember what the                  6 e-mail system was.                  7 Q. The change from Lotus to --                  8 excuse me, the change from Lotus e-mail                  9 to Lotus Notes, that's an example of a                  10 technology change that I'm thinking                  11 about.                  12 Are there other                  13 technological changes like that,                  14 technological advances that may have been                  15 adopted into the C.R. Bard compliance                  16 program during your time there?                  17 MR. BOGLE: Object to form.                  18 Overbroad.                  19 THE WITNESS: Would you like                  20 to narrow it or do we need to go                  21 through everything, everything in                  22 every area?                  23 I mean, for example, did we                  24 have a better adverse event</p>	<p style="text-align: right;">Page 108</p> <p>1 A. DEA Form 22 is a form that                  2 you have to file with the DEA when you're                  3 distributing opioids, to my recollection.                  4 But again I can go back and look at my                  5 report if you'd like. Can we go back and                  6 look at the report?                  7 Q. Oh sure.                  8 A. My recollection of Form 222,                  9 is the form that you file to DEA for                  10 distributing substances -- controlled                  11 substances.                  12 Q. Do you know who fills out a                  13 Form 222?                  14 A. I believe it varies by                  15 company, but the wholesaler.                  16 Q. The wholesaler fills out a                  17 Form 222?                  18 A. Manufacturer. You are                  19 asking me, are you asking me a specific                  20 job function, or are you asking me                  21 companies?                  22 Q. I'm asking you who would                  23 fill out a DEA Form 222?                  24 A. Depending on the company</p>
<p style="text-align: right;">Page 107</p> <p>1 detection system and signal                  2 detection system? Yes. Did we                  3 change technology? Yes. Do I                  4 remember exactly what they were                  5 and the names of all of them? No.                  6 Did it provide output                  7 information that we then utilized                  8 as part ever of our compliance                  9 efforts? Yes.                  10 BY MR. EPPICH:                  11 Q. And the event detection                  12 system -- strike that.                  13 The adverse event -- strike                  14 that again.                  15 The adverse event detection                  16 system that you just mentioned, that was                  17 one example of improved technology that                  18 Bard incorporated into their compliance                  19 system while you were there, correct?                  20 A. Correct.                  21 Q. I'd like to ask you a few                  22 questions about some terminology.                  23 A. Sure.                  24 Q. What is a DEA Form 222?</p>	<p style="text-align: right;">Page 109</p> <p>1 it's going to vary by job function,                  2 whatever function is assigned to do it.                  3 Q. Do you know who at a                  4 wholesale drug distributor would fill out                  5 a Form 222?                  6 MR. BOGLE: Object to form.                  7 Vague.                  8 THE WITNESS: Are we talking                  9 about a specific drug distributor,                  10 or are we talking drug                  11 distributors in general?                  12 BY MR. EPPICH:                  13 Q. We can take McKesson as an                  14 example. Who at McKesson fills out a                  15 form 222?                  16 A. Let me go back and look at                  17 my report, to be sure. My recollection                  18 is it was filled out by the distribution                  19 center.                  20 Q. What is a DEA Form 106?                  21 A. I don't recall what a Form                  22 106 is.                  23 Q. Have you heard the term DEA                  24 Form 106 before?</p>



<p style="text-align: right;">Page 110</p> <p>1 A. Yeah. I've heard the term          2 before. But I can't give you a precise          3 definition of the form.          4 Q. What is the Ryan-Haight Act?          5 A. Well, on that one, you've          6 got me, because I don't know.          7 Q. Are you familiar with the          8 ARCOS database?          9 A. Yes, I am familiar with the          10 ARCOS database.          11 Q. What is ARCOS?          12 A. My understanding is it is a          13 DEA database that records opioid          14 transactions.          15 Q. And what types of entities          16 are required to report ARCOS data to the          17 DEA?          18 A. I believe registrants are          19 required to do that.          20 Q. Do you know which          21 registrants in particular?          22 A. Not off the top of my head.          23 Q. Do you know what is reported          24 by these registrants to the ARCOS</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. What is CSOS?          2 A. You want to give me the          3 spelling of that so we are on the same          4 page?          5 Q. C-S-O-S.          6 A. Again, is there a specific          7 reference in the report that you would          8 like to go to, or are you just looking          9 for a general term, CSOS? I'm not sure I          10 understand your question, sir.          11 Q. Have you ever heard of CSOS          12 before?          13 A. I have seen it as an acronym          14 used to describe controlled substances          15 ordering systems, yes.          16 Q. And do you know anything          17 about CSOS other than the acronym?          18 MR. BOGLE: Object to form,          19 vague.          20 THE WITNESS: Again, can you          21 be more precise in what you're          22 looking for?          23 BY MR. EPPICH:          24 Q. How do registrants use CSOS?</p>
<p style="text-align: right;">Page 111</p> <p>1 database?          2 A. In general terms, yes. Do I          3 know exactly every single field they are          4 required to report? No, I do not.          5 Q. In general terms then?          6 A. Size, volume, customer, et          7 cetera.          8 Q. Size, volume, customer?          9 A. Of the orders. Of orders.          10 Q. And orders of what, sir?          11 A. Opioids -- controlled          12 substances.          13 Q. Are registrants required to          14 submit information on all controlled          15 substances or a subselection of          16 controlled substances to the ARCOS          17 database?          18 MR. BOGLE: Object to form.          19 THE WITNESS: Honestly I          20 didn't look at that to see what          21 the breadth of the ARCOS database          22 was. I do know that they have to          23 submit it for opioids.          24 BY MR. EPPICH:</p>	<p style="text-align: right;">Page 113</p> <p>1 A. Again, I'm not even sure I          2 know what you're talking about, per se,          3 because I'm not sure exactly, because          4 again I've seen CSOS used in different          5 acronyms to describe individual          6 registrants, controlled suspicious order          7 monitoring systems. So I'm not exactly          8 sure where you're driving to.          9 Q. Have you heard of the term          10 "Holy Trinity"?          11 A. Yeah, I have heard the term,          12 "the Holy Trinity."          13 Q. And what is the Holy          14 Trinity?          15 A. We can go find it -- we can          16 go find it in my report. I have it.          17 It's a -- it's a drug mixture or the          18 three drugs that are -- tend to be abused          19 together.          20 But I -- if you want the          21 specific drug names, we can go down and          22 find them. It's in the report.          23 Would you like me to spend          24 the time to go find it?</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. Maybe later.</p> <p>2 A. Okay.</p> <p>3 Q. Are you familiar with the</p> <p>4 closed system of distribution?</p> <p>5 A. Yes, I am familiar with the</p> <p>6 closed system of distribution.</p> <p>7 Q. You'd agree with me that</p> <p>8 entities have different roles in the</p> <p>9 control -- in the -- in the closed system</p> <p>10 of drug distribution?</p> <p>11 A. Could you be more precise</p> <p>12 when you say entities have -- what</p> <p>13 entities are we talking about? Which</p> <p>14 ones are we making comparisons between?</p> <p>15 Q. Manufacturers are part of</p> <p>16 the closed system of distribution?</p> <p>17 A. Yes, they are.</p> <p>18 Q. And their role is different</p> <p>19 than the role of distributors in that</p> <p>20 closed system, correct?</p> <p>21 MR. BOGLE: Object to form.</p> <p>22 THE WITNESS: Their</p> <p>23 requirements are exactly the same.</p> <p>24 How they implement them and what</p>	<p style="text-align: right;">Page 116</p> <p>1 more precise as to what you're</p> <p>2 asking?</p> <p>3 BY MR. EPPICH:</p> <p>4 Q. Well, pharmacies dispense</p> <p>5 pharmaceuticals to fill prescriptions</p> <p>6 written by physician -- physicians, isn't</p> <p>7 that correct?</p> <p>8 A. Pharmacies dispense</p> <p>9 prescriptions written by those who are</p> <p>10 authorized to write -- authorized</p> <p>11 prescribers can be more than physicians,</p> <p>12 as we've mentioned before. It could be</p> <p>13 nurse practitioners and physician's</p> <p>14 assistants. But, yes, they fill</p> <p>15 prescriptions provided to them by an</p> <p>16 authorized prescriber.</p> <p>17 Q. And physicians then are also</p> <p>18 part of this closed system of</p> <p>19 distribution, correct?</p> <p>20 A. Physicians and others who</p> <p>21 have prescribing privileges, yes.</p> <p>22 Q. DEA controls the closed</p> <p>23 system of distribution, correct?</p> <p>24 MR. BOGLE: Object to form.</p>
<p style="text-align: right;">Page 115</p> <p>1 they can see based on where they</p> <p>2 are in the -- in the systems can</p> <p>3 be different, yes.</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. Distributors are also part</p> <p>6 of the closed system?</p> <p>7 A. Yes, sir, they are.</p> <p>8 Q. And distributors' role is</p> <p>9 different from that of pharmacies in the</p> <p>10 closed system?</p> <p>11 A. Well, in the sense that</p> <p>12 pharmacies dispense medication and</p> <p>13 distributors don't, yes. They are a</p> <p>14 different business model.</p> <p>15 Q. Pharmacies, of course, are</p> <p>16 part of that closed system of drug</p> <p>17 distribution?</p> <p>18 A. Yes, they are.</p> <p>19 Q. Pharmacies' role is</p> <p>20 different than a physician's role in the</p> <p>21 closed system, correct?</p> <p>22 MR. BOGLE: Object to form.</p> <p>23 Vague.</p> <p>24 THE WITNESS: Could you be</p>	<p style="text-align: right;">Page 117</p> <p>1 THE WITNESS: Could you be</p> <p>2 more precise, when you say</p> <p>3 controls the closed system?</p> <p>4 That's a very broad term when you</p> <p>5 say controls.</p> <p>6 BY MR. EPPICH:</p> <p>7 Q. Well, the DEA is the</p> <p>8 governing agency that manages the closed</p> <p>9 system of drug distribution, correct?</p> <p>10 MR. BOGLE: Object to form.</p> <p>11 THE WITNESS: Again -- I'm</p> <p>12 not sure what you mean by manages,</p> <p>13 could you help me out there?</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. DEA registers all persons</p> <p>16 who handle controlled substances in the</p> <p>17 closed system of distribution?</p> <p>18 A. Yes. It requires</p> <p>19 registration.</p> <p>20 Q. And each of the -- each of</p> <p>21 the supply chain participants that we</p> <p>22 just went through must be licensed by the</p> <p>23 DEA, correct?</p> <p>24 A. Can you be more precise with</p>

<p style="text-align: right;">Page 118</p> <p>1 that question?</p> <p>2 Q. Manufacturers must be</p> <p>3 registered by the DEA in order to</p> <p>4 participate in the closed system of</p> <p>5 distribution, correct?</p> <p>6 A. In order to participate with</p> <p>7 using -- selling controlled substances,</p> <p>8 yes.</p> <p>9 Q. And distributors must be</p> <p>10 registered by the DEA?</p> <p>11 A. To distribute controlled</p> <p>12 substances, yes. If they aren't</p> <p>13 distributing controlled substances, no.</p> <p>14 Q. Pharmacies must be</p> <p>15 registered with the DEA to distribute</p> <p>16 controlled substances?</p> <p>17 A. Yes.</p> <p>18 Q. And doctors must be</p> <p>19 registered with the DEA to -- to</p> <p>20 distribute controlled substances,</p> <p>21 correct?</p> <p>22 A. That is correct.</p> <p>23 Q. DEA also controls the amount</p> <p>24 of controlled substances that are</p>	<p style="text-align: right;">Page 120</p> <p>1 transfer of the controlled substances</p> <p>2 between manufacturers, distributors,</p> <p>3 pharmacies, and prescribers, correct?</p> <p>4 MR. BOGLE: Object to form.</p> <p>5 THE WITNESS: Again, what do</p> <p>6 you mean by controls the transfer?</p> <p>7 BY MR. EPPICH:</p> <p>8 Q. What I mean is that they are</p> <p>9 the agency that monitors, regulates, and</p> <p>10 enforces the CSA and its regulations that</p> <p>11 set forth the closed system of drug</p> <p>12 distribution.</p> <p>13 MR. BOGLE: Object to form.</p> <p>14 Compound and overbroad.</p> <p>15 THE WITNESS: Could you</p> <p>16 repeat the question for me,</p> <p>17 please?</p> <p>18 BY MR. EPPICH:</p> <p>19 Q. You'd agree with me that the</p> <p>20 DEA is the agency that monitors,</p> <p>21 regulates, and enforces the Controlled</p> <p>22 Substances Act and its accompanying</p> <p>23 regulations?</p> <p>24 MR. BOGLE: Same objection.</p>
<p style="text-align: right;">Page 119</p> <p>1 produced, bought, sold, or otherwise</p> <p>2 transferred within this controlled --</p> <p>3 within this closed system of drug</p> <p>4 distribution?</p> <p>5 MR. BOGLE: Object to form.</p> <p>6 Compound.</p> <p>7 THE WITNESS: Could you</p> <p>8 rephrase the question for me?</p> <p>9 BY MR. EPPICH:</p> <p>10 Q. DEA controls the amount of</p> <p>11 controlled substances that are produced,</p> <p>12 bought, sold, or otherwise transferred</p> <p>13 within the closed system of drug</p> <p>14 distribution?</p> <p>15 MR. BOGLE: Same objection.</p> <p>16 THE WITNESS: Again, it's an</p> <p>17 overly broad question. But if</p> <p>18 you're asking me does DEA manage a</p> <p>19 quota system around certain types</p> <p>20 of products, controlled substances</p> <p>21 we are talking about, the answer</p> <p>22 is yes, they do.</p> <p>23 BY MR. EPPICH:</p> <p>24 Q. And DEA controls the</p>	<p style="text-align: right;">Page 121</p> <p>1 THE WITNESS: I agree that</p> <p>2 the DEA has primary jurisdiction</p> <p>3 when it comes -- certainly the</p> <p>4 lead agency when it comes to</p> <p>5 controlled substances, yes.</p> <p>6 BY MR. EPPICH:</p> <p>7 Q. And part of those</p> <p>8 responsibilities of the DEA is to control</p> <p>9 and manage the closed system of</p> <p>10 distribution, correct?</p> <p>11 MR. BOGLE: Object to form.</p> <p>12 THE WITNESS: Again, I'm not</p> <p>13 sure what you mean by managed.</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. What word would you be</p> <p>16 familiar with? Let me strike that.</p> <p>17 The DEA controls the amount</p> <p>18 of opioids brought into the closed system</p> <p>19 of drug distribution, correct?</p> <p>20 MR. BOGLE: Object to form.</p> <p>21 Asked and answered.</p> <p>22 THE WITNESS: I think we've</p> <p>23 covered this.</p> <p>24 They control the quota</p>

<p style="text-align: right;">Page 122</p> <p>1 system, yes.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. Let's turn in your expert</p> <p>4 report, Exhibit 2, to Page 33.</p> <p>5 A. Could you say the page</p> <p>6 again, please.</p> <p>7 Q. 33.</p> <p>8 A. Yes, sir. I think I'm</p> <p>9 there.</p> <p>10 Q. So near the top of the</p> <p>11 report, or excuse me, the top of Page 33,</p> <p>12 there's -- you have summarized a list of</p> <p>13 SOM requirements.</p> <p>14 Do you see that, listed 1</p> <p>15 through 6?</p> <p>16 A. Yes, I do see it.</p> <p>17 Q. SOM is suspicious order</p> <p>18 monitoring, correct?</p> <p>19 A. Yes, as I'm using SOM.</p> <p>20 Q. Is this a complete list of</p> <p>21 all the suspicious order monitoring</p> <p>22 requirements?</p> <p>23 MR. BOGLE: Object to form.</p> <p>24 THE WITNESS: Honestly I</p>	<p style="text-align: right;">Page 124</p> <p>1 says there, yes.</p> <p>2 Q. You would agree with me that</p> <p>3 Section 74(a) does not require -- let me</p> <p>4 strike that.</p> <p>5 Let me go ahead and mark as</p> <p>6 Exhibit Number 4 a copy of -- one second.</p> <p>7 A. No worries.</p> <p>8 MR. BOGLE: We got two days,</p> <p>9 so we are at your leisure.</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Whitelaw-4.)</p> <p>13 BY MR. EPPICH:</p> <p>14 Q. All right. Let's go ahead</p> <p>15 and mark as Exhibit 4 a copy of Section</p> <p>16 1301.74.</p> <p>17 Sir, if you could read</p> <p>18 1301.74. It says, "Before distributing a</p> <p>19 controlled substance to any person" --</p> <p>20 A. Are we reading the whole</p> <p>21 section or just a subsection? You said</p> <p>22 1301.74?</p> <p>23 Q. I'm going to go ahead and</p> <p>24 read -- I'm going to go ahead and read</p>
<p style="text-align: right;">Page 123</p> <p>1 can't tell you without going back</p> <p>2 and reading the regulations. If</p> <p>3 you want we can go through the</p> <p>4 regulations point by point, but</p> <p>5 it's a fairly robust list. I</p> <p>6 can't tell you it's a complete</p> <p>7 list.</p> <p>8 BY MR. EPPICH:</p> <p>9 Q. For each of these</p> <p>10 requirements, you cite the source for</p> <p>11 which the requirement is derived,</p> <p>12 correct?</p> <p>13 A. I do actually.</p> <p>14 Q. Let's walk through these</p> <p>15 requirements.</p> <p>16 The first one you list is,</p> <p>17 "The customer must be known to determine</p> <p>18 that the customer can lawfully receive</p> <p>19 the shipment."</p> <p>20 Do you see that?</p> <p>21 A. I do.</p> <p>22 Q. And you cite in Note 124 to</p> <p>23 21 C.F.R. 1301.74(a), correct?</p> <p>24 A. That is what the citation</p>	<p style="text-align: right;">Page 125</p> <p>1 Section (a) of 1301.74.</p> <p>2 A. Okay.</p> <p>3 Q. And I'll read it for the</p> <p>4 record. "Before distributing a</p> <p>5 controlled substance to any person who</p> <p>6 the registrant does not know to be</p> <p>7 registered to possess the controlled</p> <p>8 substance, the registrant shall make a</p> <p>9 good faith inquiry, either with the</p> <p>10 administration or with the appropriate</p> <p>11 state-controlled substances registration</p> <p>12 agency, if any, to determine that the</p> <p>13 person is registered to possess the</p> <p>14 controlled substance."</p> <p>15 Do you see that, sir?</p> <p>16 A. Yes, sir. I see that</p> <p>17 section.</p> <p>18 Q. Now, Section (a) requires</p> <p>19 the entity distributing a controlled</p> <p>20 substance to determine that the person is</p> <p>21 registered to possess the controlled</p> <p>22 substance. Isn't that what that says?</p> <p>23 A. Yes, I think that's a fair</p> <p>24 reading of it.</p>

<p style="text-align: right;">Page 126</p> <p>1 Q. So the entity distributing  2 the controlled substance needs to check  3 the registration status of the person who  4 is seeking the controlled substances,  5 correct?</p> <p>6 A. That again, I think, is a  7 fair reading.</p> <p>8 Q. And this requirement, this  9 only requirement that we see in  10 Section (a), that the distributor check  11 the registration status, is that what you  12 mean when you say, "The customer must be  13 known to determine that the customer can  14 lawfully receive the shipments"?</p> <p>15 A. I think you've overly  16 limited the section. You said  17 distributors only.</p> <p>18 What the section actually  19 says is, if you're shipping a controlled  20 substance to the person, you need to make  21 a good faith inquiry that the person  22 receiving it has a valid registration.  23 So if you're a manufacturer shipping a  24 bulk shipment to a distributor, they're</p>	<p style="text-align: right;">Page 128</p> <p>1 pulled. Is it getting -- are there  2 enforcement actions to pull that license.  3 You know, are there reasons, other  4 reasons beyond just looking for the  5 registration, per se, that would lead you  6 to conclude that you probably don't want  7 to ship the substances without further  8 inquiry at this time.</p> <p>9 Q. And where in the statute  10 does it say that -- strike that.</p> <p>11 Where in the registration  12 does it say that a registrant must look  13 to other --</p> <p>14 A. It doesn't say it in the  15 actual section. So let's be clear.  16 Where it comes from is the statute, as  17 you started to say, that you have to have  18 an effective anti-diversion program. So  19 you need to understand where your product  20 is going, including whether or not you  21 have a valid registration. It's part of  22 the larger statutory obligation to  23 maintain an effective anti-diversion  24 program.</p>
<p style="text-align: right;">Page 127</p> <p>1 going to need to make sure that your  2 distributor has a -- is licensed to  3 receive that.</p> <p>4 Q. Thank you for that  5 clarification. You're absolutely right.</p> <p>6 The Subsection (a) requires  7 the registrant to check for a valid  8 registration, correct?</p> <p>9 A. That's what it says -- says  10 there, yes.</p> <p>11 Q. And that -- that's what you  12 mean when you state, "The customer must  13 be known to determine that the customer  14 can lawfully receive the shipment." You  15 mean that the registrant needs to check  16 the registration, correct?</p> <p>17 A. Among other things, yes.  18 But that's what I'm citing to in  19 particular there, yes. If you don't know  20 who you're shipping to, how can you check  21 a registration?</p> <p>22 Q. You mentioned "among other  23 things." What other things?</p> <p>24 A. Has their license been</p>	<p style="text-align: right;">Page 129</p> <p>1 Q. The next requirement that  2 you list is, "There must be a designed  3 system." Is that correct?</p> <p>4 A. I did.</p> <p>5 Q. And then you cite to 21  6 C.F.R. 1301.74(b) for that -- for  7 support, correct?</p> <p>8 A. Mm-hmm.</p> <p>9 Q. Are there any other sources  10 that you would cite for this requirement?</p> <p>11 A. Well, we did talk about the  12 statute. So we go back to the statute of  13 what is an effective anti-diversion  14 program. I'm sure we can go through lots  15 and lots of the guidance, if you want to  16 go through -- spend time going through  17 each and every letter that the DEA has  18 written for guidance.</p> <p>19 But those are the two  20 things, like the Rannazzisi letters, that  21 come to mind -- top of mind. But no, I  22 do not have a complete and exhaustive  23 list for you.</p> <p>24 Q. Is there a reason that you</p>



<p style="text-align: right;">Page 130</p> <p>1 only cited 21 C.F.R. 1301.74(b) here in  2 Footnote 125?  3 A. Other than it states that  4 you have to design and operate a system,  5 no.  6 I mean, again, I'm not sure  7 I understand your question. I cited to  8 that because that's what it says in the  9 regulation.  10 Q. The third requirement you  11 list is, "It must be operational,"  12 correct?  13 A. Yeah.  14 Q. And again, you cite to 21  15 C.F.R. 1301.74(b)?  16 A. I do.  17 Q. Are there any other sources  18 that you can think of for this  19 requirement?  20 A. I think we covered --  21 covered it with the previous one, but we  22 can go back over it. Controlled  23 Substances Act in and of itself. Again,  24 for an effective -- for an effective</p>	<p style="text-align: right;">Page 132</p> <p>1 pattern; or, C, unusual frequency."  2 And again you cite to 21  3 C.F.R. 1301.74(b), correct?  4 A. That is correct.  5 Q. Are there any other sources  6 that you would cite for this requirement?  7 A. Again, let's go back to the  8 statute. It's necessary for an effective  9 anti-diversion program, you need to be  10 flagging and reporting and finding and  11 holding and not shipping suspicious  12 orders.  13 Q. Now, you mentioned the  14 statute. And I believe you are referring  15 to 21 C.F.R. 800; is that correct?  16 A. I don't know the exact  17 number. I believe it's the Controlled  18 Substances Act. We can go find the exact  19 statutory reference if you'd like.  20 Q. And my apologies. I think I  21 may have confused you. I said C.F.R. I  22 meant to say 21 U.S.C. 800.  23 A. Again, it is where the  24 Controlled Substances Act is codified.</p>
<p style="text-align: right;">Page 131</p> <p>1 anti-diversion program, if your system  2 doesn't work or doesn't operate, how can  3 you report anything? So you obviously  4 have to have an operational system, and  5 it has to work. You also have the  6 Rannazzisi letters and other guidance as  7 well, Chemical Handler's Manual. I mean,  8 we can go through it in a complete list.  9 But I don't have a complete  10 list for you, but those certainly would  11 come to top of mind.  12 Q. And the fourth requirement  13 that you list is, "It must identify  14 suspicious orders of controlled  15 substances."  16 Do you see that?  17 A. I do.  18 Q. And again, you cite to 21  19 C.F.R. 1301.74(b)?  20 A. Yes.  21 Q. The fifth requirement you  22 list is, "Orders can be suspicious  23 because of, A, unusual size; B,  24 substantial deviation from a normal</p>	<p style="text-align: right;">Page 133</p> <p>1 Again, if you would like to find the  2 exact section, we can go back and do  3 that.  4 Q. Is the term "suspicious  5 orders" defined in the CSA?  6 A. My understanding is the  7 closest definition that we have is  8 defined in the implementing regulations.  9 Q. Now, the final requirement  10 you list, 6, has two subparts. I'm going  11 to take them one at a time.  12 The first part of the  13 requirement is, "Once a suspicious order  14 is discovered, A, the local DEA field  15 office must be informed."  16 A. Mm-hmm.  17 Q. And for that requirement you  18 cite again to Section 1301.74(b),  19 correct?  20 A. Correct.  21 Q. And are there any other  22 sources for this requirement?  23 A. I think it's embodied in the  24 statute, if you want to go there, and</p>

Page 134

1 probably other guidance. I don't have an  
2 exhaustive list off the top of my head.  
3 Q. The second part of the  
4 requirement that you list is, "Once a  
5 suspicious order is discovered, B, the  
6 order must be prevented from being filled  
7 until it can be ascertained that the  
8 order will not be diverted."  
9 A. Mm-hmm.  
10 Q. And for this requirement you  
11 cite to the DEA 6 -- and I believe that's  
12 June 12, 2012, letter; is that correct?  
13 A. That is what I -- that is  
14 what I cited to there.  
15 Q. So the DEA's letter of  
16 June 12, 2012, is the guidance from which  
17 this requirement can be derived, correct?  
18 MR. BOGLE: Object to form.  
19 THE WITNESS: It is a place  
20 where you can find that guidance.  
21 But that guidance actually -- you  
22 know, if we look at it, if we go  
23 back again to the concept of --  
24 let's start with the top level

Page 135

1 concept.  
2 You have to have an  
3 effective program, anti-diversion  
4 program. So if you're shipping  
5 things that you think are being  
6 diverted, there's no way you can  
7 claim you have an effective  
8 anti-diversion program. It just  
9 doesn't work.  
10 So the thing has to be  
11 stopped until you can figure out  
12 whether or not you have detected  
13 something that is really you think  
14 is diversion or you don't think is  
15 diversion. And then in which case  
16 you release it and let it ship.  
17 But you can't have an  
18 effective program while you keep  
19 on shipping out the door saying,  
20 you know, it doesn't require me to  
21 do that. That doesn't work for  
22 making an effective anti-diversion  
23 program.  
24 BY MR. EPPICH:

Page 136

1 Q. So for this requirement you  
2 would look to the CSA itself and the  
3 June 12, 2012, letter as a source?  
4 A. And the regulation -- and  
5 the regulation as well. I would look to  
6 it all.  
7 Again, you're trying to read  
8 everything in an isolated context. And  
9 that's not the way compliance  
10 professionals work. We don't read things  
11 in isolated context. We look at big  
12 picture. We look at the picture across  
13 it to -- and, again, we're looking to  
14 achieve an objective. And what is the  
15 objective here that's been set out for  
16 distributors and manufacturers? It is to  
17 have an effective program to prevent  
18 diversion.  
19 So we're looking at the  
20 bigger goal of where you're trying to get  
21 to. And so yes, we're looking at  
22 guidance. We're looking at a variety of  
23 different things.  
24 But you like to read things

Page 137

1 in isolation. And that's really not how  
2 we work. We really work by reading it,  
3 looking across the spectrum.  
4 Q. And I'm just -- I'm just  
5 looking for the sources that you would  
6 refer to for this requirement 6(b) of  
7 your list of SOM requirements. And I  
8 believe you've mentioned the CSA, its  
9 regulations --  
10 A. And the guidance --  
11 Q. -- and the June 12, 2012 --  
12 A. That's one of the --  
13 Q. To --  
14 A. -- also there are other  
15 letters --  
16 MR. BOGLE: Let him  
17 finish --  
18 THE WITNESS: Sorry.  
19 BY MR. EPPICH:  
20 Q. If we -- if we could just  
21 not talk over each other?  
22 A. Sorry. I'm -- apologize.  
23 Q. That's okay. It's -- it's  
24 easy to do that in a deposition. Let me

<p style="text-align: right;">Page 138</p> <p>1 go ahead and -- and restart.  2 MR. BOGLE: Yeah, if you  3 can. Yeah.  4 BY MR. EPPICH:  5 Q. You provided to us three  6 citations as support for the SOM  7 requirement that you set forth, 6(b). I  8 believe you've identified the statute,  9 the CSA, and its accompanying  10 regulations, and the June 12, 2012, DEA  11 letter.  12 MR. BOGLE: Just object as  13 misstates the testimony.  14 MR. EPPICH: I'll move to  15 strike -- excuse me. I'll -- I'll  16 strike the question.  17 BY MR. EPPICH:  18 Q. I think you understand what  19 I'm trying to -- to ask you now.  20 What citations or what  21 support do you provide or can you provide  22 for the SOM requirement 6(b) on Page 33  23 of your report that states, "Once a  24 suspicious order is discovered, the order</p>	<p style="text-align: right;">Page 140</p> <p>1 Q. If we can turn to Page 7 of  2 your report.  3 Under the section of your  4 report titled "Compliance Standards For  5 Corporate Compliance Programs," you first  6 list the federal sentencing guidelines.  7 Do you see that?  8 A. Yes, sir, I do.  9 Q. And specifically you rely on  10 Chapter 8 of the federal sentencing  11 guidelines, correct?  12 A. I do, sir.  13 Q. Chapter 8 outlines the  14 circumstances in which the standards in  15 Chapter 8 apply; is that correct?  16 A. I'm sorry, could you restate  17 the question? I'm not sure what you're  18 asking.  19 Q. Chapter 8 outlines the  20 circumstances in which these standards  21 that are discussed in Chapter 8 apply?  22 A. It doesn't -- no, it doesn't  23 necessarily list all the circumstances in  24 which it applies. It says this is what a</p>
<p style="text-align: right;">Page 139</p> <p>1 must be prevented from being filled until  2 it can be ascertained that the order will  3 not be diverted"?  4 A. I can provide you that  5 letter. I am aware of a similar  6 statement in the Chemical Handler's  7 Manual. I'm also aware of the fact that  8 it's been stated as policy in the  9 administrate -- administrator's federal  10 registers in the Masters case. There's a  11 variety of places that I can go to give  12 you exact references.  13 But I'm also saying to you,  14 it's embodied, it was embodied in the  15 concept of having an effective  16 anti-diversion program as far back as  17 1970.  18 MS. SWIFT: Could you speak  19 up a little bit, please,  20 Mr. Whitelaw? I'm having a hard  21 time hearing.  22 THE WITNESS: I'm sorry, I'm  23 doing my best.  24 BY MR. EPPICH:</p>	<p style="text-align: right;">Page 141</p> <p>1 company should have, and it gives the  2 framework of what is -- are the standards  3 around what is considered a good and  4 effective compliance program.  5 Q. In a section entitled  6 "Applicability of Chapter 8," the federal  7 sentencing guidelines state, "This  8 chapter applies to the sentencing of all  9 organizations for felony and Class A  10 misdemeanor offenses"?  11 A. That is what the title says,  12 yes.  13 Q. The guidelines expressly  14 state that they are to be used for  15 criminal sentencing of organizations,  16 correct?  17 A. That is certainly one of its  18 purposes, yes.  19 Q. And you understand that this  20 is a civil litigation, this -- this  21 deposition is for a civil litigation,  22 correct?  23 A. Clearly.  24 Q. It's not a criminal case?</p>

<p style="text-align: right;">Page 142</p> <p>1 A. To my knowledge, no, it's  2 not a criminal case.  3 Q. And under the guideline's  4 own applicability section, the guidelines  5 are not applicable to this civil  6 litigation.  7 Would you agree?  8 MR. BOGLE: Objection.  9 THE WITNESS: No, sir, I  10 would not agree. I fundamentally  11 disagree with where you are going  12 with this.  13 The guidelines are the basic  14 framework. They are where  15 everybody starts. It's where  16 industry starts. It's where  17 compliance professionals start.  18 It's where good companies start,  19 et cetera.  20 It is the baseline. It has  21 become the de facto set of  22 standards that you start with when  23 you're looking at and assessing  24 corporate compliance programs.</p>	<p style="text-align: right;">Page 144</p> <p>1 are actually the basis that we use  2 day in and day out as consultants,  3 compliance professionals, et  4 cetera, to do our job.  5 BY MR. EPPICH:  6 Q. Are you familiar with the  7 2005 case of U.S. versus Booker?  8 A. I am familiar with the case  9 of U.S. versus Booker.  10 Q. And it's true that in U.S.  11 versus Booker, the United States Supreme  12 Court held that applying these federal  13 sentencing guidelines in a criminal  14 context is unconstitutional, did it not?  15 MR. BOGLE: Object to form.  16 THE WITNESS: I believe  17 that's an unfair reading of the  18 standard. What they said is it  19 couldn't be the only reason and be  20 used.  21 A judge can consider the  22 federal sentencing guidelines and  23 sentencing organizations. It  24 couldn't be the sole basis for</p>
<p style="text-align: right;">Page 143</p> <p>1 Now, it happens to be  2 embodied in the section that has  3 that title as we just discussed,  4 but it is not just limited to  5 criminal actions. And doing so is  6 not a good read of where the world  7 of compliance is and the way we do  8 things. Because you use it.  9 And by the way, if it were  10 only limited to criminal things,  11 then I would wonder why everybody  12 is running around out there and  13 putting in their own compliance  14 programs, trying to follow these  15 guidelines. It wouldn't make any  16 sense if you said it's only for  17 criminal.  18 People are doing it because  19 it's good business. People are  20 doing it because it's a good --  21 it's effective in maintaining  22 compliance.  23 So those standards, although  24 they are embodied in that section,</p>	<p style="text-align: right;">Page 145</p> <p>1 sentencing organizations.  2 BY MR. EPPICH:  3 Q. So the court has the  4 discretion whether or not to apply the  5 federal sentencing guidelines, correct?  6 MR. BOGLE: Object to form.  7 THE WITNESS: In what  8 context? Are we talking just a  9 criminal context, are we talking  10 about a civil context?  11 BY MR. EPPICH:  12 Q. In a --  13 A. But in -- but in general, a  14 court has discretion to use them like  15 they use other standards, yes.  16 Q. And the -- let me strike  17 that.  18 Let me go ahead and turn to  19 Page 9 of your report.  20 On Page 9, actually, the  21 middle of the page, sir, you discuss U.S.  22 versus C.R. Bard, the case of U.S. versus  23 C.R. Bard; is that correct?  24 A. I do reference it there,</p>

<p style="text-align: right;">Page 146</p> <p>1 yes.</p> <p>2 Q. And specifically your report</p> <p>3 cites to the plea agreement decision by</p> <p>4 the court in that case, right?</p> <p>5 A. It references the actual</p> <p>6 case, yes.</p> <p>7 Q. C.R. Bard is the medical</p> <p>8 device company that you used to work for,</p> <p>9 correct?</p> <p>10 A. That I used to work for,</p> <p>11 yes.</p> <p>12 Q. The FDA brought criminal</p> <p>13 charges against C.R. Bard, correct?</p> <p>14 A. That is correct.</p> <p>15 Q. And C.R. Bard pleaded guilty</p> <p>16 to 391 felonies in that case?</p> <p>17 A. I need to see the actual</p> <p>18 settlement to remember the exact number,</p> <p>19 but I think you're in the ballpark.</p> <p>20 Q. Hundreds of felonies,</p> <p>21 correct?</p> <p>22 A. It was quite a lot.</p> <p>23 Q. Now, you were the senior</p> <p>24 attorney and compliance coordinator at</p>	<p style="text-align: right;">Page 148</p> <p>1 the catheters on humans without</p> <p>2 permission from FDA, correct?</p> <p>3 MR. BOGLE: Object to form.</p> <p>4 THE WITNESS: Again, if you</p> <p>5 have a document for me to look at,</p> <p>6 I'll be happy to refresh my</p> <p>7 recollection.</p> <p>8 BY MR. EPPICH:</p> <p>9 Q. Well, do you recall if C.R.</p> <p>10 Bard was being prosecuted for illegally</p> <p>11 testing catheters on humans without</p> <p>12 permission from the FDA?</p> <p>13 A. I believe that was one of</p> <p>14 the counts. Again, I -- it's been a long</p> <p>15 time, and I would love to refresh my</p> <p>16 memory.</p> <p>17 Q. Now, C.R. Bard was -- the</p> <p>18 case that you cite of U.S. versus C.R.</p> <p>19 Bard, this was a criminal enforcement</p> <p>20 action by FDA against a medical device</p> <p>21 company, correct?</p> <p>22 A. Yes.</p> <p>23 Q. The case did not involve a</p> <p>24 wholesale drug distributor?</p>
<p style="text-align: right;">Page 147</p> <p>1 C.R. Bard at the time C.R. Bard pleaded</p> <p>2 guilty to those felonies, right?</p> <p>3 A. Yes, I was, as a matter of</p> <p>4 fact.</p> <p>5 Q. And the case that you cite</p> <p>6 here in your report on Page 9, is the</p> <p>7 court's acceptance of the plea agreement</p> <p>8 for C.R. Bard felonies. That's right,</p> <p>9 right?</p> <p>10 A. Mm-hmm.</p> <p>11 MR. BOGLE: Make sure you</p> <p>12 say yes --</p> <p>13 THE WITNESS: I'm sorry,</p> <p>14 yes.</p> <p>15 MR. EPPICH: Thank you.</p> <p>16 BY MR. EPPICH:</p> <p>17 Q. C.R. Bard pled guilty to</p> <p>18 keeping adverse information from FDA</p> <p>19 about angioplasty catheters, correct?</p> <p>20 A. That was certainly one of</p> <p>21 the counts. I don't remember all 390.</p> <p>22 If you have a document for me to look at,</p> <p>23 I'd be happy to look at it.</p> <p>24 Q. C.R. Bard illegally tested</p>	<p style="text-align: right;">Page 149</p> <p>1 A. No, sir.</p> <p>2 Q. The case did not involve a</p> <p>3 pharmaceutical manufacturer of controlled</p> <p>4 substances?</p> <p>5 A. No, sir.</p> <p>6 Q. The case did not involve the</p> <p>7 DEA?</p> <p>8 A. No, sir, it did not.</p> <p>9 Q. The case did not arise under</p> <p>10 the Controlled Substances Act?</p> <p>11 A. No, sir, it did not.</p> <p>12 Q. The case did not involve</p> <p>13 controlled substances of any kind, did</p> <p>14 it?</p> <p>15 A. No, it didn't.</p> <p>16 Q. If we can turn to Page 11.</p> <p>17 On Page 11 of your report, sir, you</p> <p>18 discuss certain guidances issued by the</p> <p>19 office of the inspector general for</p> <p>20 Health &amp; Human Services, correct?</p> <p>21 A. Yes, I do.</p> <p>22 Q. Now, these OIG guidances</p> <p>23 were issued by the Department of Health &amp;</p> <p>24 Human Services. That's correct, right?</p>



<p style="text-align: right;">Page 150</p> <p>1 A. Yes.</p> <p>2 Q. The OIG guidances were not</p> <p>3 issued by DEA, correct?</p> <p>4 A. No, they weren't.</p> <p>5 Q. And the OIG guidances don't</p> <p>6 address the Controlled Substances Act or</p> <p>7 suspicious order monitoring?</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: Could you</p> <p>10 rephrase the question, please?</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. Do the OIG guidances address</p> <p>13 the Controlled Substances Act or discuss</p> <p>14 the Controlled Substances Act?</p> <p>15 MR. BOGLE: Same objection.</p> <p>16 THE WITNESS: Not in so many</p> <p>17 words, no. But again, I would go</p> <p>18 back to the conversation that we</p> <p>19 had earlier. You're reading this</p> <p>20 in a very narrow context. In the</p> <p>21 world of compliance, we look at a</p> <p>22 lot of guidance.</p> <p>23 The OIG guidance, the Bard</p> <p>24 case, are all examples of putting</p>	<p style="text-align: right;">Page 152</p> <p>1 monitoring for controlled substances,</p> <p>2 correct?</p> <p>3 MR. BOGLE: Objection.</p> <p>4 Asked and answered.</p> <p>5 THE WITNESS: Well, as we</p> <p>6 can go back over again, you're</p> <p>7 asking a very narrow question.</p> <p>8 You are looking at it only in a</p> <p>9 very narrow framework.</p> <p>10 You are refusing to look at</p> <p>11 it in a larger context. And,</p> <p>12 therefore, it has relevance, it is</p> <p>13 important, and it helps inform</p> <p>14 decisions on how to write an</p> <p>15 effective -- put together an</p> <p>16 effective compliance program,</p> <p>17 whether it be for controlled</p> <p>18 substances or another topic.</p> <p>19 BY MR. EPPICH:</p> <p>20 Q. I appreciate that. But my</p> <p>21 question was a yes or no answer. And</p> <p>22 that was very simple and I would just</p> <p>23 appreciate it if you would answer my</p> <p>24 question.</p>
<p style="text-align: right;">Page 151</p> <p>1 good companies, whether they be</p> <p>2 wholesalers or manufacturers or</p> <p>3 whatever, on notice that</p> <p>4 compliance is important, and</p> <p>5 having an effective compliance</p> <p>6 program is important, and here's</p> <p>7 how to go about doing it.</p> <p>8 So again, reading these</p> <p>9 things in isolation, it is really</p> <p>10 a very, very technical and narrow</p> <p>11 read. And good companies don't do</p> <p>12 it that way. Good companies</p> <p>13 actually look at the entire</p> <p>14 panoply of evidence and apply it</p> <p>15 to their organizations.</p> <p>16 So they're not just thinking</p> <p>17 about this as, oh, this doesn't</p> <p>18 apply. It's not DEA. We're not</p> <p>19 looking at it that way.</p> <p>20 MR. EPPICH: I'll move to</p> <p>21 strike everything after "no."</p> <p>22 BY MR. EPPICH:</p> <p>23 Q. It's true that the OIG</p> <p>24 guidances don't discuss suspicious order</p>	<p style="text-align: right;">Page 153</p> <p>1 The OIG guidance does not</p> <p>2 discuss suspicious order monitoring of</p> <p>3 controlled substances, correct?</p> <p>4 A. And my answer, which I will</p> <p>5 go back to, is not in exquisitely</p> <p>6 excruciating detail, but does it apply to</p> <p>7 programs for controlled substances and</p> <p>8 suspicious order monitoring? I believe</p> <p>9 it does. And that is my opinion, that it</p> <p>10 does. And it informs people who are</p> <p>11 building and running and maintaining</p> <p>12 those programs how to do it.</p> <p>13 Q. And what is the basis for</p> <p>14 this opinion that you're offering?</p> <p>15 A. This opinion is based on the</p> <p>16 fact that I have done this for 30 years.</p> <p>17 I am a compliance expert. Building</p> <p>18 compliance programs that actually work</p> <p>19 and are effective is my job. Assessing</p> <p>20 whether or not other people's programs</p> <p>21 are not built to work effectively is also</p> <p>22 my job.</p> <p>23 I'm basing it on experience</p> <p>24 and I am basing it on that.</p>

<p style="text-align: right;">Page 154</p> <p>1 Q. Now, Health &amp; Human Services  2 has never issued a guidance for  3 pharmaceutical distributors, correct?  4 A. That is correct, and noted  5 it as such in my report.  6 Q. In fact, you state this, and  7 I believe it's Footnote 21 on Page 11.  8 And there you state, "To date the OIG has  9 published no specific compliance program  10 guidance document for distributors."  11 Is that -- is that accurate?  12 A. That is an accurate  13 statement. However, I also note at the  14 same time in my report, that OIG expects  15 you to look across industries at the  16 guidance and glean from those things that  17 are important and bring them home and use  18 them.  19 Q. Let's look at the last full  20 paragraph on Page 11 of your report.  21 There you state, "Although  22 OIG never established specific compliance  23 program guidance for pharmaceutical  24 distributors, a close reading of the</p>	<p style="text-align: right;">Page 156</p> <p>1 we're referring to the ones in the  2 pharmaceutical manufacturers  3 guidance, "may have also have  4 application to manufacturers and  5 other" -- "of other products that  6 may be reimbursed by federal  7 healthcare programs."  8 It's an example that the OIG  9 is saying, it shouldn't be read  10 into a vacuum, which I think we've  11 been having that discussion for  12 most of this morning.  13 BY MR. EPPICH:  14 Q. But even in this quote that  15 you just read to me, and it's on the top  16 of Page 12 of your report, the OIG does  17 not say there that the guidance applies  18 to distributors, correct?  19 MR. BOGLE: Object to form.  20 THE WITNESS: Could you be  21 more clear in exactly what you're  22 asking? Because I'm not sure what  23 you're asking.  24 BY MR. EPPICH:</p>
<p style="text-align: right;">Page 155</p> <p>1 guidance published in 2003 for  2 pharmaceutical manufacturers provides  3 many informative insights suitable for  4 distributors as well."  5 HHS has never instructed  6 pharmaceuticals distributors to use this  7 HHS OIG guidance prepared for the  8 pharmaceutical manufacturers, correct?  9 MR. BOGLE: Object to form.  10 THE WITNESS: Can you ask me  11 the question again?  12 BY MR. EPPICH:  13 Q. HHS has never instructed  14 pharmaceutical distributors to use this  15 OIG guidance that was prepared for the  16 pharmaceutical manufacturers, correct?  17 MR. BOGLE: Object to form.  18 THE WITNESS: I would  19 disagree. I would argue that if  20 you look at the top of Page 12:  21 "In addition, the compliance  22 program elements and potential  23 risk areas addressed in this  24 compliance program guidance," and</p>	<p style="text-align: right;">Page 157</p> <p>1 Q. The language that you quoted  2 on Page 12 from the OIG does not  3 specifically state that this guidance  4 applies to pharmaceutical distributors,  5 correct?  6 MR. BOGLE: Object as asked  7 and answered.  8 BY MR. EPPICH:  9 Q. You can answer again.  10 A. As I've said before, I  11 believe that that statement at the top is  12 a notice to other industries including  13 distributors that there are elements in  14 the program that they should be paying --  15 in the program guidance they should be  16 paying attention to, and incorporating  17 where -- where appropriate into their  18 programs.  19 Q. Does the word distributors  20 appear in the quote that you have on the  21 top of Page 12?  22 A. I do not see the word -- the  23 magic word distributor in the quote at  24 the top of Page 12.</p>

Page 158

1 Q. If we can turn to Page 16 of  
2 your report.  
3 On Page 16 of your report,  
4 you have a section entitled "Controlled  
5 Substances Security Manual & Suspicious  
6 Order Task Force (1997 to 2004)," correct?  
7  
8 A. I do.  
9 Q. And here you discuss the  
10 controlled substances suspicious order  
11 task force?  
12 A. I do.  
13 Q. You are aware that members  
14 of DEA's Office of Diversion Control  
15 participated in the suspicious order task  
16 force in the 1990s?  
17 A. Yes, I am.  
18 Q. Are you aware that as part  
19 of the task force DEA worked with  
20 registrants to develop an automated  
21 suspicious order tracking system?  
22 A. I know it was a topic of  
23 discussion.  
24 Q. Do you know if DEA was

Page 159

1 working with registrants in developing  
2 that system?  
3 MR. BOGLE: Object to form.  
4 Vague and overbroad.  
5 THE WITNESS: Again, what do  
6 you mean by working with?  
7 BY MR. EPPICH:  
8 Q. Well, did the DEA  
9 communicate, work with, in the  
10 development of that system?  
11 MR. BOGLE: Object to form.  
12 BY MR. EPPICH:  
13 Q. If you know.  
14 A. I was not a party to the  
15 minutes. I would assume it was a topic  
16 of discussion. But can I tell you  
17 exactly what was involved and what topics  
18 were discussed and how they were  
19 discussed, and all that, no, I can't.  
20 Q. Are you aware that the  
21 suspicious order task force produced a  
22 report in 1998?  
23 A. I am.  
24 Q. And this report outlined a

Page 160

1 system that DEA and the registrants  
2 developed?  
3 MR. BOGLE: Object to form.  
4 THE WITNESS: I know it  
5 outlined a system. Again, who  
6 developed it and what role each  
7 party played in it, I don't know.  
8 BY MR. EPPICH:  
9 Q. The system was described in  
10 the DEA's document, the suspicious order  
11 task force report in 1998, correct?  
12 A. Yes.  
13 Q. I'd like to talk about that  
14 system for a moment. Are you -- are you  
15 familiar with the system that's described  
16 in -- in that report?  
17 A. In general terms, yes.  
18 Q. Why don't we go ahead and --  
19 and mark the suspicious order task force  
20 report.  
21 MR. BOGLE: Chris, if we are  
22 shifting gears, we've been going a  
23 little over an hour again. I  
24 could use a restroom break myself,

Page 161

1 especially if we're going to a  
2 different subject here.  
3 MR. EPPICH: We can take a  
4 break, yeah. Let's go off.  
5 THE VIDEOGRAPHER: Going off  
6 the record. 11:42 a.m.  
7 (Short break.)  
8 THE VIDEOGRAPHER: Back on  
9 record at 12:02 p.m.  
10 BY MR. EPPICH:  
11 Q. Dr. Whitelaw, I'm handing  
12 you a copy of what's been marked as  
13 Exhibit 5.  
14 (Document marked for  
15 identification as Exhibit  
16 Whitelaw-5.)  
17 MR. EPPICH: And I have  
18 copies for you as well.  
19 THE WITNESS: Great, thank  
20 you. Okay.  
21 BY MR. EPPICH:  
22 Q. Exhibit 5 is a copy of the  
23 report to the U.S. Attorney General by  
24 the suspicious order task force,

<p style="text-align: right;">Page 162</p> <p>1 Comprehensive Methamphetamine Control Act          2 of 1996 and supplemental report to the          3 Attorney General.          4 Dr. Whitelaw, are you          5 familiar with this report?          6 A. I am familiar with the          7 report, yes.          8 Q. If you would, could you turn          9 to Page 42 of the report.          10 A. Do I have a minute to page          11 through the report?          12 Q. Yeah, sure.          13 A. Thanks.          14 MR. BOGLE: And while he's          15 looking at that, Chris, you said          16 Page 42?          17 MR. EPPICH: It's -- I          18 apologize. It looks -- it looks          19 to me the Bates numbers might have          20 got cut off.          21 BY MR. EPPICH:          22 Q. But I'm looking at          23 Exhibit 2. And it's -- the bottom right          24 corner says, "SOTF Report Appendix A:4."</p>	<p style="text-align: right;">Page 164</p> <p>1 for List I chemicals, correct?          2 A. Yes, it is.          3 Q. The automated tracking          4 system described on this page is for          5 Schedule II to V controlled substances as          6 set forth in the title, correct?          7 MR. BOGLE: Object to form.          8 Incomplete.          9 THE WITNESS: Could you          10 restate your question, please?          11 BY MR. EPPICH:          12 Q. The automatic tracking          13 system described on this page is for          14 Schedule II to V controlled substances as          15 set forth in the title -- the subtitle          16 that we just read, correct?          17 MR. BOGLE: Objection to          18 form. Incomplete description of          19 the document.          20 THE WITNESS: I would          21 disagree with how you're          22 characterizing it. The title does          23 say List I chemicals and Schedules          24 II to V controlled substances.</p>
<p style="text-align: right;">Page 163</p> <p>1 Were you able to find that          2 page, Dr. Whitelaw?          3 A. I was. I'm still looking at          4 the rest of the document. So give me a          5 minute, please. But, yes, I found the          6 page.          7 All right. Yeah, I'm there.          8 Q. So on Page 42 -- Page 42 of          9 the report, or what is Exhibit 2 of this          10 report, on Page SOTF Report Appendix A-4,          11 the title reads "Suspicious Order          12 Reporting System of 1998 For Use in          13 Automated Tracking Systems," correct?          14 A. That is an accurate reading          15 of that title, yes.          16 Q. And the next title, the          17 title directly below that says, "The          18 current calculation being used for List I          19 chemicals and Schedule II to V controlled          20 substances."          21 Did I read that correctly?          22 A. Yes, I think you did.          23 Q. The automated tracking          24 system that's described on this page is</p>	<p style="text-align: right;">Page 165</p> <p>1 However, if we skip down to, I          2 believe it's four on the page, and          3 you look at that note, it says,          4 "Note, Factor equals three for          5 C-II and C-III controlled          6 substances containing List I          7 chemicals."          8 I believe that a fair          9 reading of this actual document is          10 that it applies to Controls II          11 through V -- Schedule II through V          12 controlled substances to the          13 extent they contain listed          14 chemicals.          15 BY MR. EPPICH:          16 Q. I appreciate that. I wasn't          17 trying to mischaracterize the document.          18 I was simply trying just to learn or ask          19 whether or not this Exhibit 2 applied to          20 List I chemicals and Schedule II to V          21 controlled substances.          22 MR. BOGLE: Same objection.          23 THE WITNESS: I'm saying --          24 and I'm saying it applies to List</p>

Page 166

1 I chemicals, yes, and it applies  
2 to Schedules II through V only to  
3 the extent that they contain List  
4 I chemicals.  
5 BY MR. EPPICH:  
6 Q. Now, the program described  
7 in the report calculated monthly averages  
8 based on the last 12 months of  
9 purchasing, correct?  
10 A. That was a starting dataset,  
11 yes.  
12 Q. The program described in the  
13 report sets thresholds of three times the  
14 monthly average for purchases of Schedule  
15 II controlled substances?  
16 A. No, sir. It sets three  
17 times the monthly average for controlled  
18 substances containing List I chemicals.  
19 Q. The program described in the  
20 report identified orders that exceeded  
21 the thresholds on a suspicious order  
22 report, correct?  
23 A. I'm sorry. I'm not sure I  
24 understand your question.

Page 167

1 Q. Well, the program described  
2 in the report, and the thresholds that  
3 you just mentioned, the program instructs  
4 the identification of suspicious  
5 orders -- let me strike that.  
6 Let's turn to Page 17 -- 17  
7 of your report.  
8 A. Okay. Just a minute. Let  
9 me get there for you. Yes, sir. I'm  
10 here.  
11 Q. Looking at Section 5.3.2,  
12 the Chemical Handler's Manual, on Page 17  
13 of your report.  
14 Do you see that?  
15 A. Yes, sir, I do.  
16 Q. In the first sentence on  
17 this page, your report states, "The DEA  
18 created the Chemical Handler's Manual in  
19 response to the enactment of the various  
20 chemical control laws amending the  
21 original CSA, but also to provide general  
22 guidance on complying with the CSA.  
23 Did I read that correctly?  
24 A. Yes, you did.

Page 168

1 Q. So the DEA created the  
2 Chemical Handler's to provide general  
3 guidance for complying with the CSA,  
4 correct?  
5 A. That was one of its aspects,  
6 but of course the other aspect was to do  
7 with how you're handling List I  
8 chemicals. And it was all in response to  
9 the Methamphetamine Act. So that's the  
10 real context behind why the Chemical  
11 Handler's Manual came into being in the  
12 first place, but...  
13 So it was actually, in a  
14 way, a dual role.  
15 Q. In the second paragraph on  
16 this page, sir, the first sentence  
17 states, "The manual also outlined the  
18 voluntary formula for use by distributors  
19 to wholesale retail levels," correct?  
20 A. That is what -- my report  
21 says, yes.  
22 Q. And you agree that this  
23 formula was not mandatory?  
24 A. I agree to -- agree that

Page 169

1 that was the formula that was listed and  
2 stated in the manual as being voluntary.  
3 Q. And you agree that a factor  
4 of three that's discussed was also  
5 voluntary, correct?  
6 A. I believe that the factor of  
7 three that we're talking about was  
8 voluntary in regard to List I chemicals  
9 or Schedule II through V substances that  
10 contained List I chemicals yes.  
11 Q. Now, in looking at the third  
12 paragraph of your report, on Page 17. In  
13 the second and third sentences, you  
14 state, "A plain reading of Appendix E-3,  
15 is that if a Schedule II or III  
16 controlled substance does not contain a  
17 List I chemical, that factor is not  
18 applicable. Therefore, for opioid  
19 products not containing a List I  
20 chemical, that factor is not applicable."  
21 Did I read that correctly?  
22 A. Yes, you did.  
23 Q. Now, let's just take a step  
24 back for a moment. DEA never told



<p style="text-align: right;">Page 170</p> <p>1 registrants not to apply the factor of  2 three, correct?  3 MR. BOGLE: Object to form.  4 Vague and overbroad.  5 THE WITNESS: I'm not sure I  6 understand your question.  7 BY MR. EPPICH:  8 Q. Did DEA -- let me strike  9 that.  10 Are you aware of DEA ever  11 telling registrants not to apply the  12 factor of three?  13 MR. BOGLE: Object to form.  14 Vague and overbroad.  15 THE WITNESS: I think we'd  16 have to talk about in context.  17 Can you narrow the context?  18 It's such -- never, ever are  19 too broad for me to be able to say  20 one way or the other.  21 BY MR. EPPICH:  22 Q. Are you aware if DEA ever  23 told registrants that they were  24 prohibited from applying factors other</p>	<p style="text-align: right;">Page 172</p> <p>1 controlled substance's customer is  2 properly licensed to possess the  3 controlled substance. Both must also  4 take steps to know the customer." In  5 the -- "In other words, they need" -- and  6 I quote -- "to take responsible measures  7 to verify the identity of their  8 customers, understand the normal and  9 expected transactions typically conducted  10 by those customers, and consequently  11 detect those transactions that are  12 suspicious in nature."  13 Do you see that, sir?  14 A. I see that, but you didn't  15 read it correctly. It's actually "to  16 take reasonable measures to verify the  17 identity of their customers, understand  18 the normal and expected transactions  19 typically conducted by those customers,  20 and consequently detect those  21 transactions that are suspicious in  22 nature."  23 Q. And what do you cite for  24 that paragraph, sir?</p>
<p style="text-align: right;">Page 171</p> <p>1 than the factor of three?  2 MR. BOGLE: Objection.  3 Vague, and overbroad as to time.  4 THE WITNESS: I'm still not  5 sure I'm understanding what you're  6 looking for.  7 BY MR. EPPICH:  8 Q. You rely on the chemical  9 handler's in certain parts of your  10 report, don't you?  11 A. Could you explain what you  12 mean by rely on chemical handler's?  13 Q. Well, let's --  14 A. I mean, I cite to the  15 Chemical Handler's Manual, yes.  16 Q. Let's turn to page --  17 A. But I don't know what you  18 mean by rely.  19 Q. Well, let's turn to Page 26.  20 A. Okay.  21 Q. Now, on Page 26 of your  22 report, the second full paragraph reads,  23 "As a threshold matter, the distributor  24 or manufacturer must determine if the</p>	<p style="text-align: right;">Page 173</p> <p>1 A. I cite to the Chemical  2 Handler's Manual.  3 Q. So you apply the Chemical  4 Handler's Manual in this section of your  5 report, which is Section 6.1.2? You're  6 applying --  7 A. I reference it.  8 Q. You reference it?  9 A. Yes.  10 Q. What is a List I chemical?  11 A. A List I chemical is a  12 precursor that was listed in the  13 methamphetamine statute that can be used  14 to make methamphetamine.  15 Q. The DEA has said that  16 because List I chemicals are frequently  17 precursors, DEA has found that List I  18 chemicals require a greater level of  19 control than other listed chemicals. Is  20 that true?  21 A. I'd say that is a fair -- a  22 fair reading of -- of where they were  23 going, yes.  24 Q. And you acknowledge this in</p>

<p>Page 174</p> <p>1 Footnote 62 of your report, correct?</p> <p>2 It's on Page 17.</p> <p>3 A. Let me go back to Page 17</p> <p>4 and look at Footnote 62.</p> <p>5 Yes, I see that.</p> <p>6 Q. Your report then says, "The</p> <p>7 manual also outlined a voluntary formula</p> <p>8 for use by distributors to wholesale and</p> <p>9 retail levels."</p> <p>10 A. Mm-hmm.</p> <p>11 MR. BOGLE: Make sure you</p> <p>12 say yes or no.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. I'd like to talk about that</p> <p>16 voluntary formula. In your report you</p> <p>17 say that "the Factor of 3 applies to</p> <p>18 certain types of products, but not to</p> <p>19 other types of products," correct?</p> <p>20 A. What I say is it applies to</p> <p>21 List I chemicals and any List I chemical,</p> <p>22 and controlled substances that contain a</p> <p>23 List I chemical.</p> <p>24 Q. And your report says, on</p>	<p>Page 176</p> <p>1 scheduled, we'll make the</p> <p>2 assumption that that's what you're</p> <p>3 saying, then yes.</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. So this is one category,</p> <p>6 okay, this is one category of products.</p> <p>7 Your report then says,</p> <p>8 "While the manufacturers and distributors</p> <p>9 here utilize the Factor of 3 for setting</p> <p>10 thresholds for opioid products, the</p> <p>11 factor was based only on Schedule II and</p> <p>12 III controlled substances containing</p> <p>13 List I chemicals."</p> <p>14 This is the other category,</p> <p>15 right?</p> <p>16 A. I'm sorry.</p> <p>17 MR. BOGLE: Object to form.</p> <p>18 THE WITNESS: I'm not</p> <p>19 following.</p> <p>20 BY MR. EPPICH:</p> <p>21 Q. Well, your opinion is that</p> <p>22 the Factor of 3 is only permitted for</p> <p>23 Schedule II and III controlled substances</p> <p>24 containing List I chemicals.</p>
<p>Page 175</p> <p>1 Page 17, "For opioid products not</p> <p>2 containing a List I chemical, the factor</p> <p>3 is not applicable," correct?</p> <p>4 A. That is a plain reading of</p> <p>5 the appendix, yes.</p> <p>6 Q. So under your</p> <p>7 interpretation, the Factor of 3 does not</p> <p>8 apply to products that contain an opioid</p> <p>9 but not a List I chemical, correct?</p> <p>10 A. Under my representation, if</p> <p>11 it is a Schedule II through V product</p> <p>12 that does not contain a List I chemical,</p> <p>13 that Factor of 3 is not an appropriate</p> <p>14 formula.</p> <p>15 Q. So a product that contains</p> <p>16 an opioid but not a List I chemical, that</p> <p>17 would be a product that it's not</p> <p>18 applicable to, correct?</p> <p>19 MR. BOGLE: Objection.</p> <p>20 Asked and answered.</p> <p>21 THE WITNESS: I believe I</p> <p>22 asked and answered it for you.</p> <p>23 But a -- if you're saying if it's</p> <p>24 a schedule, if the opioid is</p>	<p>Page 177</p> <p>1 A. Yes. That is my opinion.</p> <p>2 Q. I just want to discuss this</p> <p>3 briefly so I can understand what</p> <p>4 you're -- what you're saying.</p> <p>5 A. I understand. And I'm</p> <p>6 trying to be -- and Chris, I'm trying to</p> <p>7 be clear for you.</p> <p>8 Q. Thank you, sir.</p> <p>9 Your -- your report says</p> <p>10 that "the Factor of 3 is permitted for a</p> <p>11 combination product that contains an</p> <p>12 opioid and a List I chemical," correct?</p> <p>13 A. I think that's a fair</p> <p>14 reading of it, yes.</p> <p>15 Q. So an opioid is part of --</p> <p>16 of this product -- the products in this</p> <p>17 category?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: I'm not sure</p> <p>20 by "this category" what we're</p> <p>21 meaning.</p> <p>22 BY MR. EPPICH:</p> <p>23 Q. Well, in a combination</p> <p>24 product that contains an opioid and a</p>

Page 178

1 List I chemical, there's an opioid in  
 2 that product, correct?  
 3 A. Under your hypothetical,  
 4 yes, that's what you just said. You said  
 5 you have an opioid that contains a List I  
 6 chemical.  
 7 Q. But the Factor of 3, in your  
 8 opinion, is not applicable for a product  
 9 that contains only an opioid, that is,  
 10 without a List I chemical?  
 11 MR. BOGLE: Objection.  
 12 Asked and answered.  
 13 You can answer.  
 14 THE WITNESS: That is --  
 15 that is my reading of the --  
 16 reading of the appendix, yes. I  
 17 think that's a plain reading of  
 18 the appendix.  
 19 BY MR. EPPICH:  
 20 Q. But the Factor of 3 as we  
 21 just discussed, that applied to a product  
 22 that contains an opioid and a List I  
 23 chemical.  
 24 Where I'm struggling is that

Page 179

1 both -- both types -- both of these  
 2 products that we talked about contain  
 3 opioids, correct?  
 4 MR. BOGLE: Object to form.  
 5 THE WITNESS: Which products  
 6 are we talking about?  
 7 BY MR. EPPICH:  
 8 Q. Let's go ahead and look at  
 9 Page 18 of your report.  
 10 A. Okay. Sure. I'm there.  
 11 Q. On Page 18 you discuss what  
 12 term the DEA industry initiative and what  
 13 the DEA called the distributor initiative  
 14 program; is that correct?  
 15 A. Yes, I -- yes, I do discuss  
 16 that.  
 17 Q. You discuss meetings between  
 18 the DEA and McKesson, Cardinal, and ABDC  
 19 in your report, correct?  
 20 A. Yes, sir, I do.  
 21 Q. You understand that these  
 22 three briefings were entitled "Internet  
 23 Pharmacy Data" by the DEA?  
 24 A. Yes, I am aware of it. I

Page 180

1 have looked at the slide decks  
 2 extensively.  
 3 Q. That -- that's because the  
 4 DEA's anti-diversion efforts at this time  
 5 were focused on internet pharmacies.  
 6 MR. BOGLE: Object to form.  
 7 BY MR. EPPICH:  
 8 Q. Correct?  
 9 MR. BOGLE: Broad.  
 10 THE WITNESS: No, I think  
 11 that's -- I think that's a poor  
 12 characterization of it. I think  
 13 DEA was always focused on  
 14 anti-diversion across the system.  
 15 I think there was a particular  
 16 heightened concern over internet  
 17 pharmacies.  
 18 But I think it's a  
 19 mischaracterization to say they  
 20 were only concerned about internet  
 21 pharmacies.  
 22 BY MR. EPPICH:  
 23 Q. But -- but you'd agree with  
 24 me that in this time period, this 2005 to

Page 181

1 2008 time period, the DEA was focusing on  
 2 internet pharmacies?  
 3 A. I would say --  
 4 MR. BOGLE: Object to form.  
 5 Go ahead.  
 6 THE WITNESS: No, I would  
 7 not agree with you. As I just  
 8 said, I think it was a focus. You  
 9 are trying to imply it's the only  
 10 focus, and I don't agree with you  
 11 on that point.  
 12 BY MR. EPPICH:  
 13 Q. Are you aware that  
 14 Mr. Rannazzisi recently testified that  
 15 from 2005 to 2008 DEA's anti-diversion  
 16 efforts were focused on internet  
 17 pharmacies?  
 18 MR. BOGLE: Object to form.  
 19 If you want to show him the  
 20 testimony, I think he can comment.  
 21 Otherwise I don't think it's fair.  
 22 It's not on his listed material.  
 23 If you want to show him something,  
 24 I'm happy to have him comment on

<p style="text-align: right;">Page 182</p> <p>1 it.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. You may answer the question.</p> <p>4 A. If you can ask --</p> <p>5 MR. BOGLE: To the extent</p> <p>6 that you can without seeing it.</p> <p>7 THE WITNESS: I'm unable to</p> <p>8 answer your question unless you</p> <p>9 actually show me the testimony. I</p> <p>10 need to see what he said. I have</p> <p>11 no idea what he said.</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. You haven't reviewed the</p> <p>14 testimony that Mr. Rannazzisi provided in</p> <p>15 this litigation?</p> <p>16 A. I haven't reviewed the --</p> <p>17 the testimony that Mr. Rannazzisi, that</p> <p>18 you're referring to. If you have</p> <p>19 something that you want me to look at,</p> <p>20 I'm more than happy to look at it right</p> <p>21 now for you.</p> <p>22 Q. Did you request that</p> <p>23 information, that deposition transcript</p> <p>24 of Mr. Rannazzisi from your plaintiffs'</p>	<p style="text-align: right;">Page 184</p> <p>1 Paragraph 2. Paragraph 2 you write,</p> <p>2 "During those meetings, the DEA told the</p> <p>3 participants that," and then you list</p> <p>4 five points, correct?</p> <p>5 A. Yes, I did.</p> <p>6 Q. Now, you never attended any</p> <p>7 of the distributor initiative briefings,</p> <p>8 did you?</p> <p>9 A. No, sir.</p> <p>10 Q. You've not spoken to anyone</p> <p>11 who attended those distributor briefings?</p> <p>12 A. I have not spoken directly</p> <p>13 with anyone who has attended those</p> <p>14 meetings, but I have reviewed the slide</p> <p>15 decks that were given to each of the</p> <p>16 defendants that are listed here as well</p> <p>17 as the corresponding deposition testimony</p> <p>18 around those meetings.</p> <p>19 Q. So the recitation in your</p> <p>20 report that we see on what occurred at</p> <p>21 these briefings is based only on your</p> <p>22 review of these presentations and your</p> <p>23 review of perhaps memorandum that the DEA</p> <p>24 submitted from Mr. Rannazzisi and</p>
<p style="text-align: right;">Page 183</p> <p>1 counsel.</p> <p>2 A. I requested any and all DEA</p> <p>3 correspondence and information regarding</p> <p>4 the DEA, and DEA policies and positions.</p> <p>5 From counsel.</p> <p>6 Q. And -- and plaintiffs'</p> <p>7 counsel has not provided you with a copy</p> <p>8 of Mr. Rannazzisi's transcript, correct?</p> <p>9 MR. BOGLE: I don't have it.</p> <p>10 THE WITNESS: I don't have a</p> <p>11 copy.</p> <p>12 MR. BOGLE: Wasn't this</p> <p>13 yesterday?</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. Let's look at Paragraph 2 on</p> <p>16 Page 18.</p> <p>17 A. Can you tell me when it was</p> <p>18 actually taken? Because, I mean, as far</p> <p>19 as I know, it hasn't -- it wasn't -- when</p> <p>20 I wrote the report, it hadn't been taken.</p> <p>21 Do you have a date on when -- did this</p> <p>22 deposition actually occurred?</p> <p>23 Q. Let's go back to Page 18 of</p> <p>24 your report, sir. I'm looking at</p>	<p style="text-align: right;">Page 185</p> <p>1 Mr. Mapes?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 BY MR. EPPICH:</p> <p>4 Q. Is that true?</p> <p>5 MR. BOGLE: Misstates</p> <p>6 testimony. You can answer.</p> <p>7 THE WITNESS: I think as I</p> <p>8 tried to be clear, but I'll try to</p> <p>9 be a little clearer, I looked at</p> <p>10 the slide decks that were provided</p> <p>11 to each of the distributors. I</p> <p>12 looked at whatever other</p> <p>13 documentation was around the</p> <p>14 characterization of those</p> <p>15 meetings, including deposition</p> <p>16 testimony, to understand what</p> <p>17 transpired in those meetings as</p> <p>18 best I could. Obviously they're</p> <p>19 before my time and I wasn't in</p> <p>20 attendance.</p> <p>21 BY MR. EPPICH:</p> <p>22 Q. Do you know of Kyle Wright?</p> <p>23 A. Do I know of Kyle Wright?</p> <p>24 Q. Do you know Kyle Wright? Do</p>

Page 186

1 you know --  
2 A. No, I do not know Kyle  
3 Wright.  
4 Q. Do you know that Kyle Wright  
5 worked at the DEA?  
6 A. As I just said, I don't know  
7 Kyle Wright, so I can't answer that  
8 question for you.  
9 Q. Did you know that Kyle  
10 Wright was a DEA diversion investigator  
11 who, along with Michael Mapes, conducted  
12 the distributor initiative briefings?  
13 A. The name rings a bell. But  
14 again, I've seen hundreds of -- is there  
15 a document that you want me to look at?  
16 I'd be happy to look at the document and  
17 refresh my recollection. I've looked at  
18 a lot of pages.  
19 Q. Did you review Mr. Wright's  
20 deposition testimony in this case?  
21 A. Again, I have to go back to  
22 my reliance list to double-check.  
23 MR. BOGLE: Do you want him  
24 to check, Chris?

Page 187

1 BY MR. EPPICH:  
2 Q. It's on Page 77.  
3 MR. BOGLE: 277.  
4 MR. EPPICH: 277. Pardon  
5 me.  
6 THE WITNESS: I did review  
7 it. I did look at it.  
8 BY MR. EPPICH:  
9 Q. Did you review Mr. Wright's  
10 deposition testimony in the case of U.S.  
11 versus \$463,497.72?  
12 A. I don't rightly recall all  
13 the pieces of Mr. Wright deposition that  
14 I reviewed. So I'm sorry I can't answer  
15 your question.  
16 Q. If you had reviewed it,  
17 would it be listed here in Appendix I of  
18 your report?  
19 A. If it's not in the  
20 depositions listed -- if I reviewed it  
21 and it's not buried in the depositions  
22 that are listed here, I would have  
23 reviewed it. It would be listed  
24 separately. But if we are talking about

Page 188

1 something that's in his actual  
2 deposition, like I said, the two volumes,  
3 I don't rightly recall everything in each  
4 volume.  
5 Q. Oh, let me be clear. I  
6 think we may be --  
7 A. I'm not sure what you're  
8 asking.  
9 Q. -- confused.  
10 So on Page 277 of your  
11 report, sir, you list the deposition of  
12 Kyle Wright, Volume I on February 28,  
13 2019, and then a second volume from  
14 March 4, 2019.  
15 These deposition transcripts  
16 are from this case, this MDL case. Do  
17 you agree with me there?  
18 A. Yes.  
19 Q. Mr. Wright gave testimony in  
20 another case. And that case is titled  
21 U.S. versus 463,497 -- let me strike  
22 that, because this is a little strange.  
23 Mr. Wright's --  
24 Mr. Wright -- are you aware that

Page 189

1 Mr. Wright gave testimony in the case of  
2 U.S. versus \$463,497.72?  
3 A. I honestly don't remember.  
4 Q. You didn't review any  
5 testimony from that case?  
6 MR. BOGLE: Object to form.  
7 THE WITNESS: Again, unless  
8 it was in the original depositions  
9 that are listed here, then the  
10 answer would have been no.  
11 BY MR. EPPICH:  
12 Q. Are you aware that  
13 Mr. Wright testified in that case under  
14 oath that the distributor briefings  
15 represented a change or transition in the  
16 DEA's guidance regarding suspicious order  
17 reporting?  
18 MR. BOGLE: Object to form.  
19 And unless you are going to show  
20 him something.  
21 If you know without looking  
22 at it, fine.  
23 THE WITNESS: I don't know  
24 without looking at it.



Page 190

1 MR. EPPICH: And I'm asking  
2 him are you aware. So I think  
3 that we're fine.  
4 BY MR. EPPICH:  
5 Q. And are you aware, sir, that  
6 Mr. Wright testified at trial in that  
7 case that the change in DEA's guidance  
8 was significant?  
9 MR. BOGLE: Same objection.  
10 THE WITNESS: If you have  
11 something for me to review I'll be  
12 happy to review it. But again  
13 without it, I can't comment.  
14 BY MR. EPPICH:  
15 Q. Are you aware or not, sir,  
16 sitting here today?  
17 MR. BOGLE: Same objection.  
18 THE WITNESS: I can't  
19 comment without seeing what you're  
20 referring to, because I don't know  
21 what you're looking at.  
22 BY MR. EPPICH:  
23 Q. Let's go ahead and mark as  
24 Exhibit 6 a document bearing the Bates

Page 191

1 Number MCK-MDL\_00496859.  
2 (Document marked for  
3 identification as Exhibit  
4 Whitelaw-6.)  
5 BY MR. EPPICH:  
6 Q. Exhibit 6 is a memorandum  
7 from the DEA titled "Internet  
8 Presentation with McKesson Corp. on  
9 September 1, 2005," from Michael Mapes to  
10 Joe Rannazzisi. And attached to that is  
11 the PowerPoint presentation that was  
12 provided to McKesson on September 1,  
13 2005.  
14 Do you see that, sir?  
15 A. Yes, sir, I do see that.  
16 Q. And in looking at the  
17 presentation that we see on the third  
18 page of this document, you stated in your  
19 report that the presentations provided to  
20 McKesson, ABDC, and Cardinal were almost  
21 identical, correct?  
22 A. That was a statement I made,  
23 yes.  
24 Q. You reviewed these

Page 192

1 presentations before, right?  
2 A. I have seen the versions of  
3 them before, yes.  
4 Q. Now, in this presentation,  
5 the DEA doesn't mention the words "know  
6 your customer," correct?  
7 A. If you'll give me time to  
8 review the entire -- to read the  
9 document, I can tell you whether or not I  
10 see the words in the presentation or not.  
11 MR. BOGLE: Yeah. I mean,  
12 if you need to.  
13 BY MR. EPPICH:  
14 Q. Thanks.  
15 A. I am -- am going to need to  
16 read it.  
17 Can you ask me the question  
18 again, please.  
19 Q. Dr. Whitelaw, have you had a  
20 chance to review the exhibit?  
21 A. I have had a chance to  
22 review the exhibit. Thank you.  
23 Q. And DEA does not mention the  
24 words "know your customer" in this

Page 193

1 presentation?  
2 A. I do not see the words "know  
3 your customer" in the presentation.  
4 Q. DEA does not set forth how a  
5 distributor must conduct due diligence of  
6 its customers in this presentation,  
7 correct?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: I'm not  
10 exactly sure what you mean by that  
11 question, but perhaps you can help  
12 me.  
13 BY MR. EPPICH:  
14 Q. Well, DEA does not tell a  
15 distributor how to identify a suspicious  
16 order in the presentation, correct?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: I still think  
19 you're being a little vague, but  
20 let me see if I can try to  
21 understand what you're asking me.  
22 You are asking me do they  
23 tell them the specific recipe list  
24 to go down to determine if an

Page 194

1 order is suspicious? Is that the  
2 question?  
3 BY MR. EPPICH:  
4 Q. You can answer that  
5 question.  
6 A. They don't give you a  
7 specific recipe list. They do say in  
8 here that you must take steps to  
9 determine when orders are suspicious and  
10 make a sales decision about them. And  
11 I'm looking at what's labeled Page 8 of  
12 that presentation list.  
13 Q. But the DEA doesn't tell  
14 distributors what steps those are or how  
15 to identify those suspicious orders,  
16 correct?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: Again, I'm  
19 going to go back and ask you to be  
20 a little more precise for me.  
21 Are we talking about  
22 providing them that they have to  
23 go down and determine what a  
24 suspicious order is, or are we

Page 195

1 talking about the specific ABCDEFG  
2 steps that you have to take?  
3 Which one are we talking about  
4 please?  
5 BY MR. EPPICH:  
6 Q. Specific steps.  
7 A. No, they do not tell you the  
8 ABCDE -- the alphabet steps.  
9 Q. The DEA does not tell a  
10 distributor it must block all suspicious  
11 orders in this presentation, do they?  
12 MR. BOGLE: Object to form.  
13 THE WITNESS: I'd have to go  
14 back to read it again to see if it  
15 talks about blocking orders. But  
16 it certainly is in the Chemical  
17 Handler's Manual, as well in the  
18 2004. So I believe it's implicit  
19 in the statements that they are  
20 making. You can't sell suspicious  
21 orders. You are not supposed to  
22 continue to distribute suspicious  
23 orders.  
24 But do I find the word block

Page 196

1 orders? No. I do not find the  
2 specific word block orders to your  
3 point.  
4 BY MR. EPPICH:  
5 Q. And just so the record is  
6 clear, you don't see the words blocked  
7 orders in this presentation that we've  
8 marked as Exhibit 6, correct?  
9 A. I did not see it. But I  
10 could go back through it again and  
11 double-check.  
12 Q. Now, looking back on Page 18  
13 of your report. Your report states,  
14 "Although couched in terms of  
15 distributors, because the requirements  
16 for manufacturers are the same, the DEA's  
17 statements are part of this initiative  
18 would apply to them too."  
19 Do you see that?  
20 A. Yes.  
21 MR. BOGLE: Object to form.  
22 BY MR. EPPICH:  
23 Q. Are you aware that these  
24 briefings, these distributor initiative

Page 197

1 briefings, were private meetings between  
2 the company and the DEA, correct?  
3 A. I know that they were  
4 meetings between DEA and a company, but I  
5 also know that they held many, many  
6 meetings with many, many people.  
7 Q. But the distributor  
8 briefings themselves were individual  
9 meetings, correct, between a company and  
10 the DEA?  
11 A. Yes, that's correct. But as  
12 we stated earlier, the slide decks and  
13 the materials that the DEA was  
14 presenting, was pretty much the same from  
15 person in the meeting -- company in the  
16 meeting, company in the meeting, company  
17 in the meeting, so they were saying the  
18 same things. They were delivering the  
19 same message is what I'm trying to say.  
20 Q. But the distributor briefing  
21 meeting between the company and the DEA,  
22 those were not public meetings, you'd  
23 agree with me, right?  
24 A. I would agree with you that

<p style="text-align: right;">Page 198</p> <p>1 they appear not to be public meetings. 2 Q. You're aware that the DEA 3 did not brief manufacturers as part of 4 the distributor briefings, correct? 5 A. Yes. I'm aware of that. 6 Q. And manufacturers did not 7 attend the meetings between DEA and the 8 distributors, correct? 9 A. Well, they certainly weren't 10 in the meeting that you've shown me. I 11 haven't seen every distributor meeting, 12 so I can't comment on them all. I can 13 comment on the one that's before me and I 14 can say they were not present. 15 Q. How would manufacturers 16 learn the requirements that the DEA 17 provided in the DEA distributor briefings 18 if these meetings were private? 19 A. Well, presumably they were 20 shared among trade associations. 21 Presumably another way is again the 22 manufacturers worked with these 23 distributors. I would assume it would be 24 communication and -- and information that</p>	<p style="text-align: right;">Page 200</p> <p>1 Let me ask a follow-up question of my 2 own. 3 Are you saying am I aware 4 that they ever issued any correspondence 5 to manufacturers that contained any of 6 the concepts that were discussed here? I 7 would say that's not a fair reading. 8 If you're saying do I know 9 that they actually put a -- put a 10 distribution notice on it and shipped 11 them the presentation? No, I have not 12 seen anything to that level of detail. 13 Q. Let's turn to Page 19 of 14 your report, if we can. And on Page 19 15 this is Section 5.3.4 titled "DEA Letters 16 to All Registrants (a/k/a The Rannazzisi 17 Letters) (2006 to 2012)." 18 A. Correct. 19 Q. Now, you write in this 20 section that "each letter focused on a 21 particular implementation topic, 22 providing DEA's current thinking about 23 what or was not effective," correct? 24 A. I do.</p>
<p style="text-align: right;">Page 199</p> <p>1 they would share amongst each other. 2 They both had a -- look, 3 they both have the common goal of having 4 an effective anti-diversion program. And 5 if there -- if distributors are being 6 asked to comply to something, it is not 7 unusual to share that information. 8 When I was in industry, we 9 shared information about regulatory 10 positions and what we were learning all 11 the time. We had a common -- we had a 12 common goal. We were trying to get to 13 the same common goal. 14 Q. But you're not aware of any 15 communication between the DEA to -- to 16 manufacturers where the contents of the 17 distributor briefings were provided? 18 MR. BOGLE: Object to form. 19 THE WITNESS: Could you be 20 more specific? 21 BY MR. EPPICH: 22 Q. I think my question is 23 specific enough. 24 A. Okay. Well, I'm confused.</p>	<p style="text-align: right;">Page 201</p> <p>1 Q. What do you mean by 2 implementation topic? 3 A. Well, I think when we talk 4 about how do you -- you know, what is -- 5 what is meant by reporting suspicious 6 orders, when should they be reported, how 7 often should they be reported. Those are 8 implementation kinds of topics. 9 Q. Now, the DEA used these 10 Rannazzisi letters to address a 11 particular topic in each letter; is 12 that -- is that right? 13 A. That was how I read them, 14 yes. 15 Q. The letters were conveying 16 updates on the DEA's current thinking? 17 MR. BOGLE: Object to form. 18 THE WITNESS: The -- could 19 you -- again, I'm not -- could you 20 repeat the question, please? 21 BY MR. EPPICH: 22 Q. You'd agree that the 23 Rannazzisi letters were expressing the 24 DEA's current thinking in providing</p>

<p style="text-align: right;">Page 202</p> <p>1 updates to the registrants, correct?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: I would say</p> <p>4 they are certainly providing DEA's</p> <p>5 thinking to registrants, yes.</p> <p>6 Whether it was current or not, I</p> <p>7 have no way of knowing. Certainly</p> <p>8 their thought process, yes.</p> <p>9 BY MR. EPPICH:</p> <p>10 Q. Do you have any reason to</p> <p>11 believe or think that it would not have</p> <p>12 been their current thinking?</p> <p>13 A. Well, I think some of the</p> <p>14 stuff that they were discussing and</p> <p>15 reminding registrants of in those letters</p> <p>16 go all the way back to 1970. So you</p> <p>17 can't call that -- at least in my mind</p> <p>18 that's not current to me. That's been</p> <p>19 around for a long time.</p> <p>20 So part of this was, you</p> <p>21 know, part of this was sort of a</p> <p>22 discussion of, was a reminder to the</p> <p>23 registrants, what are your duties and</p> <p>24 obligations.</p>	<p style="text-align: right;">Page 204</p> <p>1 Q. So your opinion sitting here</p> <p>2 today is that the information contained</p> <p>3 in the Rannazzisi letters was not new?</p> <p>4 MR. BOGLE: Objection.</p> <p>5 Asked and answered. You can</p> <p>6 answer again.</p> <p>7 THE WITNESS: My opinion is</p> <p>8 that this information was simply a</p> <p>9 restatement of positions and</p> <p>10 information that had been embodied</p> <p>11 in the original statute from way</p> <p>12 back in 1978, yes. That's my</p> <p>13 answer.</p> <p>14 BY MR. EPPICH:</p> <p>15 Q. And what is the basis for</p> <p>16 your opinion, sir?</p> <p>17 A. My expertise as a compliance</p> <p>18 expert, my reading of the record, my</p> <p>19 conversations with Mr. Rafalski. And</p> <p>20 all -- and going through the -- going</p> <p>21 through this whole report process and</p> <p>22 developing and looking at these records</p> <p>23 and reading testimony and records, et</p> <p>24 cetera, and talking to Rafalski, my</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. And -- and that's fair.</p> <p>2 Some of -- some of the information may</p> <p>3 have been a reminder, but some of the</p> <p>4 information would have also been new,</p> <p>5 correct?</p> <p>6 MR. BOGLE: Object to form.</p> <p>7 THE WITNESS: No, I don't --</p> <p>8 I don't think it was new.</p> <p>9 BY MR. EPPICH:</p> <p>10 Q. Is that your opinion?</p> <p>11 A. I don't really think it was</p> <p>12 new. I think it was all there. What may</p> <p>13 be new to the point you're trying to make</p> <p>14 is it's the first time that you've</p> <p>15 actually seen them write it down,</p> <p>16 potentially. But I don't think the</p> <p>17 concepts that are embedded in the</p> <p>18 Rannazzisi letters are in any way, shape,</p> <p>19 or form new. I think they've been there</p> <p>20 all along.</p> <p>21 Again, we start from the</p> <p>22 top. What is an effective anti-diversion</p> <p>23 program, and we work from there. That's</p> <p>24 the goal.</p>	<p style="text-align: right;">Page 205</p> <p>1 expertise in this area, et cetera.</p> <p>2 Q. Let's look at Page 20 of</p> <p>3 your report. On Page 20 in this</p> <p>4 section -- this is Section 5.3.5.</p> <p>5 Masters Pharmaceutical case.</p> <p>6 Now in this section, you</p> <p>7 discuss this Masters Pharmaceutical</p> <p>8 decision, correct?</p> <p>9 A. I do.</p> <p>10 Q. In the first paragraph, and</p> <p>11 I'm looking at the first sentence, your</p> <p>12 report says, "The opinion of DEA's acting</p> <p>13 administrator, Chuck Rosenberg, provides</p> <p>14 guidance on the determination of exactly</p> <p>15 when an order of unusual size, frequency,</p> <p>16 or pattern is discovered as suspicious";</p> <p>17 is that correct?</p> <p>18 A. That is what I said, yes.</p> <p>19 Q. Your opinions rest on</p> <p>20 positions taken by the acting</p> <p>21 administrator, Chuck Rosenberg, in the</p> <p>22 Masters Pharmaceutical case?</p> <p>23 MR. BOGLE: Objection.</p> <p>24 Vague and overbroad.</p>

Page 206

1 THE WITNESS: You want to  
2 define what you mean by rest?  
3 BY MR. EPPICH:  
4 Q. You rely on the Masters  
5 Pharmaceutical case, right?  
6 A. It is one factor of a series  
7 of factors, as I said to you before, that  
8 I looked at in formulating, like any good  
9 compliance officer would do -- I looked  
10 at the history, I've looked at where it's  
11 come from, I've looked at previous  
12 guidance, previous decisions. Yes, it's  
13 one data point, shall we say.  
14 Q. Chuck Rosenberg became the  
15 acting administrator of DEA in 2015; is  
16 that correct?  
17 A. I have no idea when Chuck  
18 Rosenberg became the acting  
19 administrator. It wasn't relevant or  
20 germane to this discussion.  
21 Q. Well, you're aware that he  
22 was not the acting administrator before  
23 the Masters decision came out, right?  
24 A. Again, it's not -- wasn't --

Page 207

1 no, I was not, nor is it relevant or  
2 germane to the opinion I was giving.  
3 What's relevant and germane is what he  
4 actually wrote down in his opinion and  
5 that he was the acting administrator at  
6 the time that he wrote that opinion.  
7 Those are what was -- that  
8 was what was germane.  
9 Q. Mr. Rosenberg's opinion in  
10 Masters Pharmaceuticals that you cited in  
11 your report was published in the Federal  
12 Register in September of 2015, correct?  
13 A. Correct.  
14 Q. And the DC Circuit Court  
15 opinion, the court of appeals opinion, of  
16 the Masters Pharmaceuticals case issued  
17 in 2017, correct?  
18 A. That is correct.  
19 Q. An opinion issued by a DEA  
20 administrator does not apply  
21 retroactively, does it?  
22 MR. BOGLE: Object to form.  
23 THE WITNESS: I'm not sure I  
24 understand your question.

Page 208

1 BY MR. EPPICH:  
2 Q. Well, my question is whether  
3 or not the opinions issued in the Federal  
4 Register via DEA administrator do not  
5 apply retroactively.  
6 MR. BOGLE: Same objection.  
7 BY MR. EPPICH:  
8 Q. For example, the Masters  
9 decision was published in 2015, in  
10 September of 2015. You wouldn't expect  
11 the decision -- the DEA to apply the  
12 decision of Masters Pharmaceuticals  
13 retroactively, to dates and events before  
14 September of 2015, would you?  
15 MR. BOGLE: Object to form.  
16 Vague and overbroad.  
17 THE WITNESS: Again, I'm  
18 still not sure I'm getting where  
19 you're going.  
20 I'm not sure of the question  
21 that you're asking me.  
22 BY MR. EPPICH:  
23 Q. Do regulatory decisions by  
24 administrative law judges apply

Page 209

1 retroactively, or are they applied  
2 forward looking?  
3 MR. BOGLE: Object to form.  
4 I think it's vague and overbroad.  
5 Calls for speculation.  
6 THE WITNESS: Yeah, I can't  
7 answer that for you. I'm sorry.  
8 BY MR. EPPICH:  
9 Q. You don't know sitting here  
10 today whether or not decisions are -- by  
11 courts are applied retroactively?  
12 MR. BOGLE: Same objections.  
13 BY MR. EPPICH:  
14 Q. Let's turn to Page 20.  
15 A. It's a vague -- it's a  
16 vague -- it's a vague question, and I  
17 can't answer it unless you are going to  
18 be a little more specific for me.  
19 Q. Let's move on. We'll go to  
20 Page 20, sir.  
21 A. Okay.  
22 Q. Back on Page 20. Still on  
23 Section 5.3.5 in the Masters  
24 Pharmaceutical case.



<p style="text-align: right;">Page 210</p> <p>1 A. Where are we now, please?</p> <p>2 Q. Page 20.</p> <p>3 A. Page 20. Yeah, I'm there.</p> <p>4 Got it.</p> <p>5 Q. Section 5.3.5?</p> <p>6 A. Mm-hmm.</p> <p>7 Q. And I'm looking at the</p> <p>8 second paragraph.</p> <p>9 A. Okay.</p> <p>10 Q. And there you acknowledge</p> <p>11 that the regulations do not expressly</p> <p>12 define what is meant by "when</p> <p>13 discovered."</p> <p>14 Did I read that correctly?</p> <p>15 A. Yes, you did read that</p> <p>16 correctly.</p> <p>17 Q. And if we turn to Page 21 of</p> <p>18 your report, you state --</p> <p>19 A. Where are you? I'm on 21.</p> <p>20 But where on 21, please?</p> <p>21 Q. I'm looking in the second</p> <p>22 paragraph, sir, and I'm about four lines</p> <p>23 down. You say, "Therefore, based on the</p> <p>24 guidance provided by acting Administrator</p>	<p style="text-align: right;">Page 212</p> <p>1 the order that has flagged of any red</p> <p>2 flags. And if you can, then you can go</p> <p>3 ahead and ship it and not report it. If</p> <p>4 you can't, you should still not report</p> <p>5 it -- or I'm sorry, you should still</p> <p>6 report it, but still not ship it. And</p> <p>7 you can continue on with your</p> <p>8 investigation point from that point on.</p> <p>9 But you can't sit there and do an</p> <p>10 investigation forever.</p> <p>11 Q. And it's your opinion that</p> <p>12 registrants have about a week to --</p> <p>13 A. I just think a week's a</p> <p>14 reasonable amount of time to determine</p> <p>15 whether you've got a fat-fingered order</p> <p>16 or whether you've got another sort of</p> <p>17 clerical error to that perspective to at</p> <p>18 least make the decision. And again,</p> <p>19 we're talking about -- so let us be</p> <p>20 clear. We're talking about, they have a</p> <p>21 point in time, about a week, to actually</p> <p>22 get that information to DEA.</p> <p>23 So here, I think I have a</p> <p>24 suspicious order I can't clear, or --</p>
<p style="text-align: right;">Page 211</p> <p>1 Rosenberg's conclusion in the Masters</p> <p>2 case, it is my opinion that this</p> <p>3 investigatory period is less than a</p> <p>4 week."</p> <p>5 A. Yes.</p> <p>6 Q. So your opinion is that</p> <p>7 registrants have a week to determine if</p> <p>8 an order is suspicious and should be</p> <p>9 reported to DEA? Is that your testimony?</p> <p>10 A. No. I think -- I think if</p> <p>11 you read what was being said here was</p> <p>12 fairly clear. You have a choice as a</p> <p>13 registrant. You can decide that you get</p> <p>14 something that's suspicious and decide</p> <p>15 that you don't want to do anything with</p> <p>16 it. You don't ship it. You cancel it.</p> <p>17 You dump it. You don't want to</p> <p>18 investigate it. You report that to DEA</p> <p>19 when you make that decision.</p> <p>20 What I'm saying to you is I</p> <p>21 do believe you have a period of time, and</p> <p>22 I believe it's consistent with the way</p> <p>23 DEA has applied the rules, to at least</p> <p>24 determine whether or not you can clear</p>	<p style="text-align: right;">Page 213</p> <p>1 But I don't think that that</p> <p>2 says that that's the end of the</p> <p>3 investigation and you have to walk away</p> <p>4 from the shipment. I think you can</p> <p>5 continue to investigate after that week's</p> <p>6 time.</p> <p>7 Q. Well, how did you decide on</p> <p>8 a week as being the reasonable time</p> <p>9 period for the investigation?</p> <p>10 A. Well, actually, if you go</p> <p>11 back and you read the opinion, when you</p> <p>12 read it pretty closely. It's pretty</p> <p>13 clear that it gives three different ways</p> <p>14 of measurement. One is a day, one is a</p> <p>15 month, and one is a week. And he says a</p> <p>16 month is too long. A day is too short.</p> <p>17 A week is in the middle.</p> <p>18 Plus if you look at other</p> <p>19 regulatory constructs such as, you know,</p> <p>20 suspicious order -- I'm sorry, adverse</p> <p>21 events and others, you know, a week is a</p> <p>22 reasonable amount -- is a fairly long</p> <p>23 period of time and a reasonable amount of</p> <p>24 time if you put the effort in to</p>

<p style="text-align: right;">Page 214</p> <p>1 determine whether you think you can clear  2 the order from suspicion.  3 Q. Has the DEA ever offered  4 guidance to registrants that one week is  5 a sufficient period of time to conduct  6 diligence on orders?  7 A. I am unaware of them  8 actually putting a time frame in it. The  9 regulation, as you know, says, when  10 discovered. But I think a fair reading  11 also of the DEA's points about they don't  12 want a lot of white noise, in other words  13 they don't want fat fingered orders.  14 They don't want you simply to report  15 things just for the sake of reporting  16 them also factors in here -- so there's  17 a -- I believe you have a window of time  18 to make a determination of whether you  19 think the thing is still suspicious or  20 not. And you're not reporting clerical  21 errors.  22 They don't want to have  23 that. They've been pretty clear that  24 they didn't want to know about clerical</p>	<p style="text-align: right;">Page 216</p> <p>1 verifiable and documented means."  2 A. Yes.  3 MR. BOGLE: Objection.  4 Misstated the -- I think you  5 missed a word or two there.  6 BY MR. EPPICH:  7 Q. Okay. I think we are on the  8 same page --  9 MR. BOGLE: I think he knows  10 where you are reading from.  11 THE WITNESS: I know where  12 you're reading from.  13 BY MR. EPPICH:  14 Q. Sir, not -- not every  15 flagged order by an automated system is  16 suspicious, correct?  17 MR. BOGLE: Object to form.  18 THE WITNESS: How are we  19 defining the term "suspicious"?  20 Are we talking about that you have  21 a suspicion that you need to do  22 further investigation? I would  23 say every flagged order that comes  24 out of the system requires you to</p>
<p style="text-align: right;">Page 215</p> <p>1 errors.  2 Q. Let's go back to Page 21 of  3 your report, sir. And I'm in the second  4 paragraph. In the second line of that  5 paragraph towards the end, "However, it  6 is reasonable to permit a brief  7 investigatory period to avoid the  8 submission of reports that have been  9 flagged by the system but clearly are not  10 suspicious as determined through  11 verifiable and documented means."  12 Did I read that correctly?  13 A. I'm not sure exactly where  14 you are. Can you read it to me again?  15 Q. Yes, sir. I apologize for  16 that. I'm on the second line of  17 paragraph --  18 A. Got it.  19 Q. So, "However it is  20 reasonable to prepare a brief  21 investigatory period to avoid the  22 submission of reports that have been  23 flagged by the system but clearly are not  24 suspicious as determined through</p>	<p style="text-align: right;">Page 217</p> <p>1 do extra work to figure out  2 whether or not there's an issue or  3 not.  4 BY MR. EPPICH:  5 Q. Not every order above a  6 fixed volume is suspicious, correct?  7 MR. BOGLE: Object to form.  8 THE WITNESS: Could you be  9 more specific?  10 BY MR. EPPICH:  11 Q. Well, say you have a  12 threshold set for a given pharmacy and a  13 given base code of drug.  14 Not every order that exceeds  15 that threshold is suspicious, correct?  16 MR. BOGLE: Object to form.  17 THE WITNESS: It's an awful  18 vague hypothetical. You're  19 saying -- again I'm not exactly  20 sure what you're -- what you're  21 trying to inquire about.  22 BY MR. EPPICH:  23 Q. Well, you'd agree with me  24 that when an automated system -- an</p>

<p style="text-align: right;">Page 218</p> <p>1 automated system flags an order, perhaps 2 because that order is above that 3 threshold, that a registrant has to look 4 at the context of the order and the 5 customer, correct? 6 MR. BOGLE: Object to form. 7 THE WITNESS: I would say 8 that the -- my answer to your 9 question will be that the 10 registrant needs to examine the 11 order and understand why the flag 12 happened and determine whether or 13 not that's a -- something that 14 is -- something as simple as a 15 clerical error or something more 16 serious. 17 BY MR. EPPICH: 18 Q. And to do that they would 19 look at the customer, correct? 20 A. I think it's one factor 21 among many. 22 Q. They'd also look at the 23 context of the order, wouldn't they? 24 A. I think that's another</p>	<p style="text-align: right;">Page 220</p> <p>1 Page 25, the last sentence of the first 2 paragraph reads: "Thus, if there is no 3 documentation showing what is claimed was 4 accomplished, the reasonable presumption 5 is that it was not accomplished." 6 Did I read that correctly? 7 A. Yes, I believe you did. 8 Q. Now, your report does not 9 cite to the regulations or the statute 10 that DEA issued -- that governed how long 11 a registrant must maintain written 12 documentation such as suspicious order 13 reports, correct? 14 MR. BOGLE: Object to form. 15 THE WITNESS: Well, again, 16 without seeing the exact code 17 sections you're referring to, I 18 can't answer your question. 19 Do you have something in 20 particular you want me to look at? 21 BY MR. EPPICH: 22 Q. Are you aware that the DEA 23 has issued a regulation that governs the 24 length of time that written records must</p>
<p style="text-align: right;">Page 219</p> <p>1 factor. But not the only factors 2 necessarily. 3 Q. Let's look at Page 25 of 4 your report quickly. On Page 25 of your 5 report, you are discussing written 6 documentation. And at the bottom of 7 Page 25 you say, and this, this is 8 actually the very last full paragraph on 9 the page, sir, in the first sentence. 10 "Thus, if there is no 11 documentation showing what is claimed, 12 the reasonable presumption is that it was 13 not accomplished." 14 Do you see that? 15 A. Yes, I do. 16 MR. BOGLE: I object. It 17 says "what is claimed is 18 accomplished." You missed a 19 couple of words there. 20 MR. EPPICH: I'm sorry. Let 21 me -- let me strike that and I'll 22 restart. 23 BY MR. EPPICH: 24 Q. Sir, on the bottom of</p>	<p style="text-align: right;">Page 221</p> <p>1 be maintained by a registrant? 2 A. I am aware -- 3 MR. BOGLE: Objection. 4 Vague. Overbroad. 5 You may answer. 6 THE WITNESS: I am aware the 7 DEA has a regulation on the books 8 that talks about certain types of 9 documentation to be kept for 10 certain periods of time. 11 BY MR. EPPICH: 12 Q. And are you aware of the 13 specific regulation I'm referring to with 14 respect to the Controlled Substances Act 15 and the suspicious order monitoring 16 programs? 17 MR. BOGLE: Object to form. 18 Misstates the document. 19 THE WITNESS: Can you give 20 me the regulation? I'll be happy 21 to tell you whether I know it or I 22 don't. 23 BY MR. EPPICH: 24 Q. Just asking, just sitting</p>

<p style="text-align: right;">Page 222</p> <p>1 here today, are you aware, sir?</p> <p>2 MR. BOGLE: Same objection.</p> <p>3 THE WITNESS: And I don't</p> <p>4 mean to be argumentive, but I'm</p> <p>5 really confused. Since there are</p> <p>6 lots of regulations out there, I</p> <p>7 would really like to know what it</p> <p>8 is you're looking at so that we</p> <p>9 can have a real conversation on</p> <p>10 it.</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. I understand. Let me -- let</p> <p>13 me just try and clarify.</p> <p>14 A. Okay.</p> <p>15 Q. Do you know how long the DEA</p> <p>16 requires registrants to maintain due</p> <p>17 diligence files in a suspicious order</p> <p>18 monitoring program?</p> <p>19 MR. BOGLE: Objection.</p> <p>20 Misstates the regulation itself.</p> <p>21 THE WITNESS: As I said to</p> <p>22 you, I am familiar with a record</p> <p>23 retentions regulation, but could I</p> <p>24 see the actual regulation?</p>	<p style="text-align: right;">Page 224</p> <p>1 part must be kept by the registrant and</p> <p>2 be available for at least two years from</p> <p>3 the date of such inventory or records for</p> <p>4 inspection and copying by authorized</p> <p>5 employees of the administration."</p> <p>6 Did I read that correctly?</p> <p>7 A. Yeah, I think you did.</p> <p>8 Q. So there's a two-year</p> <p>9 recordkeeping requirement for -- for</p> <p>10 inventory or records under the DEA</p> <p>11 regulations applicable to the CSA.</p> <p>12 That's what this says, doesn't it?</p> <p>13 A. No, sir. That's not what</p> <p>14 this regulation says.</p> <p>15 Q. What does this regulation</p> <p>16 say to you, sir?</p> <p>17 A. This regulation says that</p> <p>18 there is a minimum of two years. It says</p> <p>19 for at least two years.</p> <p>20 Q. Have you discussed Section</p> <p>21 1304.04(a) with anyone from the DEA?</p> <p>22 A. No, I have not.</p> <p>23 Q. Have you discussed Section</p> <p>24 1304.04 with Mr. Rafalski?</p>
<p style="text-align: right;">Page 223</p> <p>1 BY MR. EPPICH:</p> <p>2 Q. Sitting here today, you do</p> <p>3 not know that time frame?</p> <p>4 MR. BOGLE: Objection.</p> <p>5 Misstates his testimony.</p> <p>6 THE WITNESS: I didn't say</p> <p>7 that. I said I needed to look at</p> <p>8 the regulation.</p> <p>9 BY MR. EPPICH:</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Whitelaw-7.)</p> <p>13 BY MR. EPPICH:</p> <p>14 Q. I'm marking as Exhibit 7 a</p> <p>15 copy of 21 C.F.R. 1304.04.</p> <p>16 A. Thank you.</p> <p>17 Q. Dr. Whitelaw, are you</p> <p>18 familiar with Section 1304.04?</p> <p>19 A. Yes, sir, I am.</p> <p>20 Q. So I'm looking at</p> <p>21 1304.04(a). It says, "Except as provided</p> <p>22 in Paragraphs (a)(1) and (a)(2) of this</p> <p>23 section, every inventory and other</p> <p>24 records required to be kept under this</p>	<p style="text-align: right;">Page 225</p> <p>1 A. Don't rightly recall that we</p> <p>2 had a conversation on it. We may have.</p> <p>3 I don't recall off the top of my head.</p> <p>4 Q. Have you done any research</p> <p>5 into the legislation history of Section</p> <p>6 1304.04?</p> <p>7 A. Again, no, I have not.</p> <p>8 Q. Sitting here today it's your</p> <p>9 opinion that Section 1304 requires a</p> <p>10 registrant to keep documents for a</p> <p>11 minimum of two years. Is that what I'm</p> <p>12 hearing?</p> <p>13 MR. BOGLE: Object to form.</p> <p>14 THE WITNESS: It says for --</p> <p>15 I think --</p> <p>16 MR. BOGLE: Go ahead.</p> <p>17 THE WITNESS: I think the</p> <p>18 plain reading of the section which</p> <p>19 you just read to me, I believe the</p> <p>20 key words you're looking for, it</p> <p>21 says "for at least two years from</p> <p>22 the date of such records." And</p> <p>23 "at least" does not mean just two.</p> <p>24 At least, my reading of it</p>

<p style="text-align: right;">Page 226</p> <p>1 and understanding of it, unless  2 I'm missing something, it's -- it  3 means it could be more than two.  4 MR. EPPICH: Is this a good  5 time to take our lunch break?  6 MR. BOGLE: Yeah, that's  7 fine.  8 THE VIDEOGRAPHER: Off the  9 record, 1:04 p.m.  10 - - -  11 (Lunch break.)  12 - - -  13 A F T E R N O O N S E S S I O N  14 - - -  15 THE VIDEOGRAPHER: Back on  16 the record at 1:58 p.m.  17 - - -  18 EXAMINATION (Cont'd.)  19 - - -  20 BY MR. EPPICH:  21 Q. Dr. Whitelaw, let's turn to  22 Page 28 of your report.  23 A. Sure.  24 Q. And I'm looking in Section</p>	<p style="text-align: right;">Page 228</p> <p>1 materials to support the attributes you  2 identify, correct?  3 A. There are no -- there are no  4 footnotes there, if that's what you're  5 asking me.  6 Q. No cite -- that is what I'm  7 asking you. Thank you.  8 And what is your support for  9 each of the attributes that you identify  10 in Section 6.2.1?  11 A. Well, again, the attributes  12 build off of the previous sections that  13 we spent a lot of time on, both from a  14 corporate compliance and a controlled  15 substances compliance program, as well as  16 my more than 30 years experience doing  17 this, as an -- in designing and building  18 programs, and what runs and what's  19 effective and what, you know, isn't  20 effective, as well as my discussions with  21 Mr. Rafalski and my review of all the  22 documents in this case and information in  23 this case.  24 Q. So it's fair to say that the</p>
<p style="text-align: right;">Page 227</p> <p>1 6.2.1, attributes.  2 A. I see where you are. Yeah.  3 Q. Now, sir, the first sentence  4 in the subsection says, "Within the  5 context of a controlled substances  6 compliance program, I would expect a good  7 anti-diversion program for both a  8 manufacturer and a distributor to have  9 the following attributes."  10 Do you see that?  11 A. Yes, sir, I do.  12 Q. And in the section you then  13 list what your report describes as  14 attributes of a good anti-diversion  15 program, correct?  16 A. It defines attributes of  17 what I would expect to see from a good  18 anti-diversion compliance program, yes.  19 Q. And it includes the sections  20 integration, high-level individual, and  21 then resources.  22 A. Yes, I see them.  23 Q. Now, in looking at  24 Subsection 6.2.1, you do not cite any</p>	<p style="text-align: right;">Page 229</p> <p>1 attributes listed on Pages 28 and 29 are  2 based on your knowledge and expertise  3 over your career, correct?  4 MR. BOGLE: Objection.  5 THE WITNESS: I think that's  6 a narrow reading of what I said.  7 I said that was an element of it,  8 plus all the other work that I had  9 done in this case, plus my  10 conversations with Mr. Rafalski,  11 et cetera.  12 BY MR. EPPICH:  13 Q. Now, let's go to Section  14 6.3.1.  15 A. Section 6.3.1.  16 Q. This is on Page 30 of your  17 report.  18 A. Okay.  19 Q. And it's another section  20 entitled attributes.  21 A. I understand.  22 Q. And in the first sentence,  23 the first sentence of this subsection,  24 you state, "Within the context of a</p>



<p style="text-align: right;">Page 230</p> <p>1 controlled substances compliance program,                  2 I would expect the written standards and                  3 a good anti-diversion program for both a                  4 manufacturer and a distributor to have                  5 the following attributes."                  6 Then you list in what you                  7 describe as the written standards of a                  8 good anti-diversion program, correct?                  9 A. Yes.                  10 Q. And here you cite one source                  11 in this section for the written standard                  12 attributes; is that correct?                  13 A. I cite one example, yes.                  14 And it's -- I believe you're -- are you                  15 referring to Footnote 120?                  16 Q. I am. I am.                  17 A. Okay.                  18 Q. The source that you cite is                  19 a 2011 PowerPoint presentation from Mike                  20 Kunkle?                  21 A. Mm-hmm.                  22 MR. BOGLE: Make sure you                  23 say yes or no.                  24 THE WITNESS: Yes, it is.</p>	<p style="text-align: right;">Page 232</p> <p>1 You don't have to have, you know, a                  2 degree in learning. You don't have to be                  3 an education specialist. You can                  4 actually get guidance, pretty decent                  5 guidance, on how to build programs,                  6 training programs on your own by just                  7 simply going out and Googling.                  8 Q. And the presentation also                  9 didn't mention controlled substances, did                  10 it?                  11 A. Again, as I think we just                  12 covered, it was being cited for a                  13 different reason. And no, it did not                  14 take into account controlled substances.                  15 It was being cited for the fact that                  16 instructional design principles are                  17 fairly readily available and easy to                  18 find.                  19 Q. Would you turn to Page 34 of                  20 your report. This is Section 6.4.1.                  21 Again titled "Attributes." Section 6.4.1                  22 spans the pages of 34, 35, 36 and 37; is                  23 that correct?                  24 A. Give me a minute to check</p>
<p style="text-align: right;">Page 231</p> <p>1 BY MR. EPPICH:                  2 Q. Now, I looked at this                  3 presentation. And the author describes                  4 the presentation as a, quote, "very basic                  5 primer I once created to teach a staff of                  6 technical writers about instructional                  7 design."                  8 A. Right.                  9 Q. The PowerPoint didn't                  10 mention anything about wholesale                  11 pharmaceutical distributors, did it?                  12 A. No, sir, it did not.                  13 Q. Did it mention anything                  14 about pharmaceutical manufacturers?                  15 A. No, sir, it did not. But it                  16 wasn't being cited for those points.                  17 What it was being cited for was the fact                  18 that organizational design techniques and                  19 how to build good training programs and                  20 how to design them for learning for                  21 adults, it's readily available                  22 information that people can go out and                  23 research on their own. You don't have to                  24 have a degree in instructional design.</p>	<p style="text-align: right;">Page 233</p> <p>1 the page numbers. So what was your                  2 question again?                  3 Q. I just want to make sure                  4 that I'm reading the report correctly.                  5 Section 6.4.1 spans pages 34, 35, 36, and                  6 onto 37; is that correct?                  7 A. Correct. That is correct.                  8 That is correct.                  9 Q. Now, going back to Page 34.                  10 In the first sentence of this subsection                  11 your report states, and this is about                  12 halfway through the first sentence of the                  13 first paragraph -- "I would expect the                  14 monitoring, auditing, and investigations                  15 program for a robust distributor                  16 anti-diversion program to have the                  17 following attributes."                  18 Do you see that, sir?                  19 A. I do.                  20 Q. And over the course of                  21 Pages 34, 35, 36, and -- and half of 37                  22 in this subsection, you do not cite any                  23 sources for these attributes, do you?                  24 A. There are no footnotes, no,</p>

Page 234

1 there are not.  
2 Q. And again the attributes  
3 listed in this section are based on your  
4 knowledge and experience and -- is that  
5 accurate?  
6 A. Yes. It's based on my  
7 knowledge, experience, the data that I  
8 have reviewed, the information I have  
9 reviewed, my conversations with  
10 Mr. Rafalski. All of the above.  
11 Q. Let's go ahead and turn to  
12 Page 38. Section -- on page 38, you see  
13 Section 6.5.1 titled "Attributes"?  
14 A. I do.  
15 Q. And in this -- in this  
16 subsection, the first sentence reads,  
17 "Within the context of a controlled  
18 substances compliance program, I would  
19 expect the corrective action and risk  
20 assessment processes for both a robust  
21 distributor and manufacturer  
22 anti-diversion program to have the  
23 following attributes."  
24 A. Mm-hmm.

Page 235

1 Q. And then you identify  
2 Number 1, "Corrective Actions"; Number 2,  
3 "Risk Assessments." Do you see those,  
4 sir?  
5 A. I do see them.  
6 Q. And again, you cite no  
7 sources for any of these sentences in  
8 this section, do you?  
9 A. There are no footnotes  
10 associated with those sections. But I  
11 think a fair reading, again if you read  
12 my report, if you happen to go back up,  
13 for example, let's flip to Page 37, and  
14 we look at the section entitled  
15 "Corrective Actions & Risk Assessments,"  
16 and you read down there, you'll notice a  
17 great deal of sources cited.  
18 So the way I organized each  
19 of these sections, sir, was we started  
20 out with a general discussion about  
21 what -- what's available from the  
22 standards perspective and cited to them.  
23 And then we got into some specifics.  
24 Okay. So this is what it

Page 236

1 says. So now how would you translate  
2 that, which is what I do for a living.  
3 That's the work I do is, here are the  
4 standards, how do we apply them and make  
5 an effective compliance program.  
6 Q. And so in this section, sir,  
7 which is Section 6.5, "Corrective Actions  
8 & Risk Assessments," you reviewed the  
9 documents that are cited in  
10 Footnotes 132, 133, 134, 135, and 136.  
11 And using your experience and knowledge,  
12 you prepared the attributes that we see  
13 in Section 6.5.1?  
14 A. Correct.  
15 Q. And is that how you came up  
16 with the attributes that we see listed  
17 across all these various sections from  
18 Pages 28 to 42?  
19 MR. BOGLE: Objection.  
20 Vague and overbroad.  
21 THE WITNESS: I'm not sure I  
22 know what you're asking. Could  
23 you be more specific?  
24 BY MR. EPPICH:

Page 237

1 Q. We can go through them, each  
2 one at a time, that's fine.  
3 Why don't we turn to page --  
4 Page 41 of your report. And Page 41, do  
5 you see Section 6.6.3, sir?  
6 A. I will when I get there.  
7 I'm not there yet. Hang on a second.  
8 Which section are you  
9 looking for me to find?  
10 Q. Subsection 6.6.3.  
11 A. I do see it. Yes, I do.  
12 Q. And -- and that section is  
13 titled, "Attributes," sir?  
14 A. That section is titled  
15 "Attributes."  
16 Q. And this section concerns  
17 attributes of a disciplined system for  
18 employees, distributor customers and  
19 manufacturer customers, correct?  
20 A. Yes, that's a fair reading.  
21 Q. And you list what you  
22 believe are the attributes for such a  
23 program here in Section 6.6.3?  
24 A. Yes.

<p style="text-align: right;">Page 238</p> <p>1 Q. And once again, in  2 Section 6.6.3, you cite to no sources for  3 any of the attributes in the section,  4 correct?  5 A. Well, I think we had that  6 conversation, but I think you need to go  7 back, and a fair reading of the sources  8 and support for that, although not every  9 item is -- it starts with 6.6,  10 "Accountability - Consistent  11 Enforcement," over on Page 39.  12 Translates over on Page 40. And  13 continues all the way over to Page 41.  14 Q. So the attributes that you  15 provide in Section 6.6.3, in preparing  16 those, you would have considered the  17 sources cited in Footnote 137, 138, 139,  18 140, 141, 142, 143 and 144, and based on  19 your experience and -- and knowledge,  20 prepared the attributes that we see in  21 Section 6.6.3?  22 A. They would have been --  23 those were some of the things that I did  24 consider and that I have cited to there.</p>	<p style="text-align: right;">Page 240</p> <p>1 you would like to show me?  2 Q. Are you aware that  3 Mr. Rafalski said these things?  4 A. I'm not sure in what -- in  5 what context you are referring to. So  6 perhaps if you can give me some context  7 around it and show me a document, perhaps  8 I can comment further for you.  9 Q. The context was when  10 Mr. Rafalski was asked about your  11 conversations with him.  12 A. And when was Mr. Rafalski  13 asked about those conversations? Can you  14 be more specific, please?  15 Q. You're -- sitting here  16 today, you are not aware that he said  17 these words? It's a pretty simple yes or  18 no question.  19 A. Pretty simple yes or no  20 question is can you show me the context  21 and where you are deriving those words  22 from. Would you please show me the  23 document?  24 Q. Now, we established earlier</p>
<p style="text-align: right;">Page 239</p> <p>1 And there would have been other documents  2 that I read as well. But the sources and  3 support are there. And they derive these  4 attributes from those sources based on my  5 experience as a compliance expert. Which  6 was what I was asked to do.  7 Q. Now, you -- sir, you  8 referenced conversations with  9 Mr. Rafalski as helping form your  10 opinions on the attributes that we have  11 just discussed. Are you aware that  12 Mr. Rafalski, when asked about your  13 conversations with him, said, "I really  14 didn't see any connection between what  15 his," meaning your opinion, "was going to  16 be and my opinion. But at the request of  17 plaintiffs' counsel we had a couple of  18 discussions."  19 Are you aware that  20 Mr. Rafalski said that?  21 A. Is there something in  22 particular you would like me to review  23 and look at? I haven't seen a document  24 to that effect. Is there a document that</p>	<p style="text-align: right;">Page 241</p> <p>1 that you never worked for the DEA,  2 correct?  3 A. You did establish earlier I  4 have not had the honor of working for the  5 DEA.  6 Q. And you've never worked at a  7 wholesale distributor or a chain  8 pharmacy?  9 A. That is correct.  10 Q. You've never developed a  11 compliance program currently in use by a  12 chain pharmacy?  13 A. No, I have not designed a  14 compliance program that is in use by a  15 chain pharmacy.  16 Q. And you've never designed a  17 controlled substances compliance program  18 currently in use by a pharmaceutical  19 manufacturer, correct?  20 A. I believe we did have a bit  21 of discrepancy on that. I can't comment  22 on that, because I don't know what's in  23 place since I left some of my former  24 employers.</p>

Page 242

1 Q. Turn to Page 43 of your  
 2 report.  
 3 A. Yes, sir. Yep.  
 4 Q. On Page 43, we're in  
 5 Section 7, which is titled "Measuring  
 6 What Good Looks Like."  
 7 A. Yes.  
 8 Q. Do you see that?  
 9 A. I do.  
 10 Q. In this section, there's a  
 11 Figure 2 that is titled "Compliance  
 12 Maturity & Program Effectiveness Model."  
 13 A. Yep.  
 14 Q. The figure is a little hard  
 15 for me to read. Do you have a legible  
 16 version maybe that you use to -- to  
 17 create this figure?  
 18 A. I'd have to -- if I do, I  
 19 don't know where it is right now. I  
 20 don't have it handy.  
 21 Q. Well, did you -- there's no  
 22 citation listed for this figure. Did you  
 23 create this Figure 2, sir?  
 24 A. Yes, I actually did create

Page 243

1 Figure 2. But it's based on a model and  
 2 models that are used in, throughout the  
 3 compliance sector, to describe where you  
 4 are on a continuum of maturity level.  
 5 It's a basic measurement tool. It's used  
 6 by lots of people.  
 7 Q. And have you -- have you  
 8 used this model and specifically Figure 2  
 9 in any other case?  
 10 A. More --  
 11 MR. BOGLE: Object to form.  
 12 Go ahead.  
 13 THE WITNESS: Can you be  
 14 more specific when you say any  
 15 other case?  
 16 BY MR. EPPICH:  
 17 Q. Well, have you used Figure 2  
 18 in any of your other work as an expert  
 19 witness?  
 20 MR. BOGLE: Object to form.  
 21 THE WITNESS: As an expert  
 22 witness in a litigation? Can you  
 23 be -- again --  
 24 BY MR. EPPICH:

Page 244

1 Q. Yes, sir.  
 2 A. -- be more -- what do you  
 3 mean by that?  
 4 Q. As an expert in a  
 5 litigation, have you used Figure 2  
 6 before?  
 7 A. Have I used Figure 2 before  
 8 as an expert in a litigation. The answer  
 9 is no, because I haven't been an expert  
 10 in a litigation before. As a compliance  
 11 expert in providing assessments and  
 12 advice and counsel to clients, yes, I  
 13 have used this before.  
 14 Q. Have you published Figure 2  
 15 in any publications, any articles?  
 16 A. No, I have not.  
 17 Q. Do you know if anyone other  
 18 than yourself has used a scale such as  
 19 the one we see here in Figure 2?  
 20 A. Yes, I've seen it before.  
 21 MR. BOGLE: Hold on. Hold  
 22 on. Let him finish the question.  
 23 THE WITNESS: Sorry.  
 24 BY MR. EPPICH:

Page 245

1 Q. You're fine. It's hard  
 2 sometimes.  
 3 MR. BOGLE: Can you restate  
 4 the question for him just so we're  
 5 clear. I think he jumped on you.  
 6 MR. EPPICH: I will. I'm  
 7 trying to restate it in my head  
 8 first.  
 9 MR. BOGLE: Okay. That's  
 10 fine.  
 11 BY MR. EPPICH:  
 12 Q. Dr. Whitelaw, are you aware  
 13 of anyone who has ever used a scale such  
 14 as the one that you prepared in Figure 2  
 15 to measure how a distributor complies  
 16 with the Controlled Substances Act and  
 17 its associated regulations?  
 18 A. Not in that context, no.  
 19 Q. Now, looking at -- looking  
 20 at your model in Figure 2, is there a  
 21 point system or some other system that  
 22 you apply to evaluate the maturity of the  
 23 compliance program?  
 24 A. There is not a strict

<p style="text-align: right;">Page 246</p> <p>1 quantitative methodology. It's more of a  2 qualitative assessment.  3 Q. And does your report reflect  4 the nature of the qualitative assessment  5 to move from say foundational to  6 maturing, to advancing, to leading?  7 A. Yeah. I think if you look  8 at the bullet points underneath there,  9 and also if you look at the attributes  10 that we discussed before, you will come  11 up with that.  12 Q. So the attributes that we  13 reviewed from Pages 28 to 42 and then the  14 bullet points that we see here under  15 Figure 2.  16 A. Right. They're all combined  17 together.  18 Q. Now, have you applied Figure  19 2, your model, to the compliance programs  20 that are used by the defendants in this  21 litigation?  22 A. Yes. I believe we can go  23 find the page citations. Yes, it was  24 used.</p>	<p style="text-align: right;">Page 248</p> <p>1 BY MR. EPPICH:  2 Q. Now, just one more question  3 on the Figure 2 before I -- before I move  4 on. I was wondering, for each of the  5 bullet points that we see under each of  6 these categories, do you cite to any  7 support for the statements in those  8 bullet points?  9 MR. BOGLE: Object to form.  10 THE WITNESS: I'm not sure I  11 know what you're asking me. Are  12 you asking are there any  13 footnotes?  14 BY MR. EPPICH:  15 Q. Well, I'm asking -- and more  16 generally, let me just ask you a  17 question. Let me -- let me just strike  18 all this, and I'll ask you a new  19 question.  20 What is the support for each  21 of the -- let me strike that. I think we  22 already got this. Pardon me.  23 Let me -- let's turn to your  24 supplemental report for a moment.</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. It was used by yourself,  2 sir?  3 A. Yes, sir.  4 Q. Now, sir, do you plan to use  5 and rely on your model that we see in  6 Figure 2 at trial?  7 A. It's in my report, so  8 therefore it's subject to be used, yes.  9 I'm not sure I understand your question.  10 Q. I think you did. You  11 answered it sufficiently. Thank you so  12 much.  13 Will you expect to use a  14 more legible version of this figure at  15 trial?  16 MR. BOGLE: We can blow it  17 up for you after the depo, if that  18 will helps.  19 MR. EPPICH: That would be  20 great, Brandon. Thank you.  21 MR. BOGLE: If that's your  22 only question, I can help you with  23 that one.  24 MR. EPPICH: Thank you, sir.</p>	<p style="text-align: right;">Page 249</p> <p>1 A. Okay. Yep.  2 Q. Now, if you can turn to  3 Page 1 with me.  4 A. With "Introduction" at the  5 top?  6 Q. Yes, sir.  7 A. Okay.  8 Q. You have a section entitled  9 "Rochester Drug Cooperative." It's  10 Section 2.  11 Do you see that?  12 A. Yes, sir, I do actually.  13 Q. Now, was it your idea to  14 include a section on the Rochester Drug  15 Cooperative in your report or did the  16 plaintiffs' attorney suggest this to you?  17 A. It was mine. I thought it  18 was germane to the work that I had done;  19 therefore, in an interest of making sure  20 the court had the best possible  21 information, because again I'm working  22 for the court, I thought this would be --  23 was germane and should be included.  24 Q. When did you decide to</p>



<p style="text-align: right;">Page 250</p> <p>1 include it in a supplemental report?</p> <p>2 A. After I -- this occurred and</p> <p>3 all happened after the original report</p> <p>4 was issued. I don't have a precise date</p> <p>5 for you, but it would have been after the</p> <p>6 original report was issued.</p> <p>7 Q. And when you decided to</p> <p>8 include it in a supplemental report, were</p> <p>9 you already planning to supplement your</p> <p>10 report with other data or information?</p> <p>11 A. I don't rightly recall.</p> <p>12 Q. If we can turn to Page 2.</p> <p>13 And underneath your table, or in</p> <p>14 Section A, which is titled "General</p> <p>15 Framework Employed By the DOJ," you have</p> <p>16 a table. And then that's a paragraph</p> <p>17 below the table that reads, "It appears</p> <p>18 that the DOJ applied a similar framework</p> <p>19 to assess RDC's anti-diversion efforts.</p> <p>20 It also" --</p> <p>21 Did I read that correctly?</p> <p>22 A. Sorry. Could you read that</p> <p>23 back to me again?</p> <p>24 Q. Yes. "It appears that the</p>	<p style="text-align: right;">Page 252</p> <p>1 Rochester plea agreement?</p> <p>2 MR. BOGLE: Objection.</p> <p>3 Asked and answered.</p> <p>4 THE WITNESS: Again, it</p> <p>5 appears that they took the</p> <p>6 framework that's in effect a</p> <p>7 compliance program out of the</p> <p>8 federal sentencing guidelines and</p> <p>9 applied that against the conduct</p> <p>10 that they had observed.</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. Do you have any citation or</p> <p>13 support for your statement that it</p> <p>14 appears DOJ applied the federal</p> <p>15 sentencing guidelines to the Rochester</p> <p>16 plea agreement?</p> <p>17 A. Other than reading all of</p> <p>18 the statement of facts and checking it</p> <p>19 off against the elements of an effective</p> <p>20 compliance program, I'm not sure exactly</p> <p>21 what you're looking for, sir.</p> <p>22 Q. Is it your testimony that in</p> <p>23 the statement of facts, it states that</p> <p>24 the DOJ --</p>
<p style="text-align: right;">Page 251</p> <p>1 DOJ applied a similar framework to assess</p> <p>2 RDC's anti-diversion efforts."</p> <p>3 Do you see that, sir?</p> <p>4 A. Yes, sir, I do.</p> <p>5 Q. DOJ did not apply the</p> <p>6 federal sentencing guidelines in the</p> <p>7 Rochester plea agreement, correct?</p> <p>8 A. I'm not sure I follow the</p> <p>9 question, please.</p> <p>10 Q. Well, my question is, did</p> <p>11 the DOJ apply the federal sentencing</p> <p>12 guidelines in the Rochester plea</p> <p>13 agreement, if you know?</p> <p>14 A. What the DOJ appears to have</p> <p>15 applied is the framework for what is in</p> <p>16 effect a compliance program that is</p> <p>17 derived out of the federal sentencing</p> <p>18 guidelines. So that's what it appears</p> <p>19 that they did. And by looking at how</p> <p>20 they analyzed the statement of facts.</p> <p>21 Q. Well, do you know -- do you</p> <p>22 know for a fact, sir, as you're sitting</p> <p>23 here today, whether or not DOJ applied</p> <p>24 those sentencing guidelines in the</p>	<p style="text-align: right;">Page 253</p> <p>1 A. No, it's my --</p> <p>2 Q. -- applied -- applied the</p> <p>3 federal sentencing guidelines to the</p> <p>4 Rochester plea agreement?</p> <p>5 A. No. It's my testimony that</p> <p>6 it appears they used the same elements</p> <p>7 that are in the federal sentencing</p> <p>8 guidelines that are the framework for an</p> <p>9 effective compliance program and assessed</p> <p>10 Rochester Drug Cooperative against that</p> <p>11 framework.</p> <p>12 Q. Did the DOJ cite to the</p> <p>13 federal sentencing guidelines in the plea</p> <p>14 agreement, sir?</p> <p>15 A. If you have the plea</p> <p>16 agreement I'll be happy to re-review it.</p> <p>17 I can't recall without seeing the</p> <p>18 document.</p> <p>19 Q. You don't know as you sit</p> <p>20 here today?</p> <p>21 MR. BOGLE: Objection.</p> <p>22 Asked and answered.</p> <p>23 You can answer again.</p> <p>24 THE WITNESS: I would have</p>

<p style="text-align: right;">Page 254</p> <p>1 to see the document, please.</p> <p>2 BY MR. EPPICH:</p> <p>3 Q. Do you intend to offer any</p> <p>4 other opinions about Rochester Drug</p> <p>5 Cooperative other than those listed in</p> <p>6 your supplemental report, sir?</p> <p>7 A. Again, based on -- unless</p> <p>8 any information changes, obviously as</p> <p>9 we've said from the beginning, I reserve</p> <p>10 the right to alter my opinions should new</p> <p>11 evidence or additional evidence or</p> <p>12 additional information come forward.</p> <p>13 Q. But sitting here today, you</p> <p>14 have no other opinions about the</p> <p>15 Rochester Drug Cooperative other than</p> <p>16 what we find in your supplemental report,</p> <p>17 correct?</p> <p>18 A. Sitting here today, yes. I</p> <p>19 believe what I have included in my</p> <p>20 supplemental report is applicable to the</p> <p>21 work that I've already done and that --</p> <p>22 that's as far as I've gone.</p> <p>23 Q. If we could turn to Page 6</p> <p>24 of your supplemental report.</p>	<p style="text-align: right;">Page 256</p> <p>1 patients must be registered with the DEA.</p> <p>2 Do you remember that testimony earlier</p> <p>3 today?</p> <p>4 A. I do remember our discussing</p> <p>5 the closed system, yes.</p> <p>6 Q. And do you remember how each</p> <p>7 of the manufacturers, distributors,</p> <p>8 pharmacies, and prescribers must be</p> <p>9 registered with the DEA --</p> <p>10 A. Yes, I do remember that</p> <p>11 conversation.</p> <p>12 MR. BOGLE: Let him finish.</p> <p>13 BY MR. EPPICH:</p> <p>14 Q. And it's true that none of</p> <p>15 those individuals or entities can</p> <p>16 lawfully handle opioids without the DEA</p> <p>17 registration, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. Now, if we can turn to</p> <p>20 Page 128 of your report.</p> <p>21 A. Of the original report?</p> <p>22 Q. Yes, sir. Of the original</p> <p>23 report.</p> <p>24 A. Okay. Thank you. 128.</p>
<p style="text-align: right;">Page 255</p> <p>1 And here we have Section 4,</p> <p>2 titled "DOJ Updated Guidance on</p> <p>3 Evaluating Corporate Compliance</p> <p>4 Programs."</p> <p>5 Did I read that correctly?</p> <p>6 A. You did.</p> <p>7 Q. Your report does not mention</p> <p>8 any particular defendant in your section</p> <p>9 on DOJ's updated guidance, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Your report does not offer</p> <p>12 any opinions applying the DOJ updated</p> <p>13 guidance to any defendant, correct?</p> <p>14 A. No, sir, it does not.</p> <p>15 Q. Do you intend to offer any</p> <p>16 opinions about the DOJ updated guidance</p> <p>17 that are not in your report?</p> <p>18 A. Again, not unless facts and</p> <p>19 circumstances change. But not at this</p> <p>20 moment in time.</p> <p>21 Q. We talked earlier about the</p> <p>22 closed system of distribution. And we</p> <p>23 talked, and we discussed how every entity</p> <p>24 involved with distributing opioids to</p>	<p style="text-align: right;">Page 257</p> <p>1 Okay.</p> <p>2 Q. Now, this is Section 11.2,</p> <p>3 the "Executive Summary." Here you</p> <p>4 criticize registrants for requesting</p> <p>5 guidance from DEA, do you not?</p> <p>6 MR. BOGLE: Object to form.</p> <p>7 THE WITNESS: Could you be</p> <p>8 more specific on what it is you're</p> <p>9 pointing to?</p> <p>10 BY MR. EPPICH:</p> <p>11 Q. Sure. Let -- why don't we</p> <p>12 look at the fourth paragraph on Page 128.</p> <p>13 It's the fourth full paragraph.</p> <p>14 A. Right.</p> <p>15 Q. And it says, "Expanding on</p> <p>16 the" -- "on that notion of dialogue with</p> <p>17 the DEA, AmerisourceBergen developed the</p> <p>18 misguided narrative that it was entitled</p> <p>19 to regular communications with the DEA,</p> <p>20 including having DEA supply it with</p> <p>21 information on diversionary customers and</p> <p>22 review its systems."</p> <p>23 Do you see that, sir?</p> <p>24 A. I do see that.</p>

Page 258

1 Q. Are you aware that  
2 registrants asked DEA for guidance on how  
3 to design their suspicious order  
4 monitoring programs?  
5 MR. BOGLE: Object to form.  
6 Vague and ambiguous.  
7 THE WITNESS: Can you be a  
8 bit more specific?  
9 BY MR. EPPICH:  
10 Q. Why don't you answer my  
11 question and we'll see if it takes us in  
12 the direction that I'm -- that I'm  
13 looking to go.  
14 A. Well, I'm confused exactly  
15 what you're asking me. So perhaps you  
16 can restate the question.  
17 Q. Are you aware or are you not  
18 aware that registrants asked DEA for  
19 guidance on how to design their  
20 suspicious order monitoring programs?  
21 MR. BOGLE: Object to form.  
22 THE WITNESS: I am aware  
23 that there was -- were  
24 conversations with DEA about the

Page 259

1 systems.  
2 BY MR. EPPICH:  
3 Q. Are you aware that  
4 registrants asked DEA for guidance on due  
5 diligence investigations of customers?  
6 MR. BOGLE: Object to form.  
7 THE WITNESS: In general  
8 terms, yes.  
9 BY MR. EPPICH:  
10 Q. Should registrants have not  
11 asked the DEA for guidance on the  
12 diligence investigations of customers?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Are you  
15 saying -- could you be more  
16 specific what you're asking me?  
17 BY MR. EPPICH:  
18 Q. In -- in your opinion,  
19 should registrants have asked the DEA for  
20 guidance on the diligence investigations  
21 of their customers?  
22 MR. BOGLE: Object to form.  
23 THE WITNESS: Are you asking  
24 in general terms about how to do a

Page 260

1 due diligence across all  
2 customers, or are you talking  
3 about specific customers? I can't  
4 tell from the question you're  
5 asking me.  
6 BY MR. EPPICH:  
7 Q. My apologies. I'm asking in  
8 general terms.  
9 Generally speaking, is it  
10 your opinion that a registrant should be  
11 able to ask the DEA for guidance on due  
12 diligence investigations of their  
13 customers?  
14 A. On how to do due diligence  
15 investigations of their customers? Is  
16 that the question?  
17 Q. Yes, sir.  
18 A. Yes, my general opinion is  
19 you should be able to ask a question.  
20 Q. Are you aware that  
21 registrants asked DEA for guidance on  
22 what constituted a suspicious order?  
23 MR. BOGLE: Object to form.  
24 THE WITNESS: Again, can you

Page 261

1 be more specific on what they  
2 were -- when you say guidance,  
3 guidance is a very nebulous term.  
4 BY MR. EPPICH:  
5 Q. For example, how to identify  
6 a suspicious order?  
7 A. Yes. I am aware that they  
8 have asked for guidance in that regard,  
9 yes.  
10 Q. And is it your opinion that  
11 registrants should be able to ask DEA for  
12 guidance on how to identify a suspicious  
13 order?  
14 A. It's my -- my opinion that  
15 if you are not sure what the requirements  
16 are, you should always ask the question.  
17 I don't think it's inappropriate to ask a  
18 question. You may not get the answer.  
19 You may not get a response. But you can  
20 ask a question. I don't -- I'm not sure  
21 there's anything wrong with asking  
22 questions. I'm not sure where you're --  
23 I'm not sure what your question is.  
24 Q. And it's your opinion that

<p style="text-align: right;">Page 262</p> <p>1 if the registrants ask the DEA questions          2 such as the ones we've discussed, that          3 the DEA should provide a response,          4 correct?          5 MR. BOGLE: Object to form.          6 THE WITNESS: What type          7 of -- could you be more specific          8 as the type of response you are          9 asking for?          10 BY MR. EPPICH:          11 Q. The DEA should answer          12 questions of the registrants, correct?          13 A. Well, it would be more          14 specific. Saying "I'm not going to          15 provide you with a response" is in fact a          16 response. I don't mean to be pedantic.          17 But I am trying to understand what you're          18 asking.          19 Q. Should the DEA provide a          20 substantive answer to the question?          21 MR. BOGLE: Object to form.          22 Overbroad.          23 THE WITNESS: I would say          24 that's outside the scope of my</p>	<p style="text-align: right;">Page 264</p> <p>1 by substantive response.          2 Q. So is the answer to my          3 question, yes, the DEA should provide          4 substantive response to registrants'          5 questions when they are trying to develop          6 their suspicious order monitoring          7 systems?          8 MR. BOGLE: Objection.          9 Asked and answered.          10 THE WITNESS: It depends on          11 what you mean by substantive          12 response. I am struggling --          13 seriously struggling, Chris, with          14 your question because it's a very          15 broad -- you know, substantive is          16 very broad. And I'm not sure          17 exactly what you are asking.          18 BY MR. EPPICH:          19 Q. Should the DEA -- and let me          20 try and be more specific.          21 If a registrant who is          22 developing a suspicious order monitoring          23 system asks the DEA, how do I identify a          24 suspicious order, is it your opinion that</p>
<p style="text-align: right;">Page 263</p> <p>1 expertise as to whether they          2 should or should not provide a          3 substantive response.          4 BY MR. EPPICH:          5 Q. Well, as a registrant trying          6 to develop their suspicious order          7 monitoring program, and as a registrant          8 who has asked the DEA for example how to          9 identify a suspicious order, is it your          10 opinion that the DEA should provide a          11 substantive response to the registrant's          12 question?          13 A. I'm having a hard time          14 answering your question, because in my          15 opinion they have provided substantive          16 responses. They've provided guidance to          17 you. It's there in the regulations,          18 so...          19 Because I'm not exactly sure          20 what you're looking for, other than --          21 you know, is your substantive response          22 that you go back and look at the existing          23 guidance? Yeah, that's a substantive          24 response. So I'm not sure what you mean</p>	<p style="text-align: right;">Page 265</p> <p>1 the DEA should tell or -- tell the          2 registrant how to identify that          3 suspicious order?          4 A. Again, the difficulty -- the          5 challenge and the difficulty for what          6 you're asking is the regulation says a          7 suspicious order is of unusual size,          8 unusual frequency, and unusual pattern.          9 That, in a way, you can argue is a how.          10 If DEA responded, in your          11 hypothetical -- let's use your          12 hypothetical. DEA responded to that          13 person and said, "Look, go back to the          14 regulation and look," I would say that is          15 a substantive response, and that's a          16 substantive answer to your question that          17 you've asked.          18 Q. And if the registrant was          19 still confused by the response from the          20 DEA as to the clarity of the definition          21 of suspicious order and the regulation,          22 is it your opinion that the DEA should          23 try to clarify its response to the          24 registrant?</p>

Page 266

1 MR. BOGLE: Object to form.  
2 THE WITNESS: Again, I think  
3 we're going down an overly broad  
4 road. I'm not sure where you're  
5 trying -- could you be a lot more  
6 specific, and I'll try to answer  
7 your question.  
8 BY MR. EPPICH:  
9 Q. Do you agree that the DEA  
10 should do everything it can to prevent  
11 diversion?  
12 A. I think DEA should do  
13 everything it can to effectuate the  
14 mandate that it has been given.  
15 Q. And included in that mandate  
16 is to prevent the diversion of controlled  
17 substances, correct?  
18 A. Actually, the burden is  
19 actually on the registrants to prevent --  
20 have an effective anti-diversion program.  
21 Q. Is it your opinion sitting  
22 here today that the DEA has no role or  
23 responsibility in preventing diversion of  
24 controlled substances?

Page 267

1 MR. BOGLE: Objection.  
2 Misstates testimony.  
3 THE WITNESS: That's not  
4 what I said. And what I'm saying  
5 to you is, the registrant has the  
6 responsibility, an undelegable  
7 duty under the -- under the  
8 Controlled Substances Act and the  
9 regulations, to have an effective  
10 anti-diversion program.  
11 Does DEA have a role in  
12 oversight, enforcement, whatever?  
13 Yes, they do.  
14 BY MR. EPPICH:  
15 Q. Would you agree that greater  
16 collaboration between DEA and industry  
17 could help reduce diversion?  
18 MR. BOGLE: Object to form.  
19 BY MR. EPPICH:  
20 Q. Let me -- let me strike that  
21 question.  
22 Would you agree that greater  
23 collaboration between DEA and industry  
24 could help prevent diversion?

Page 268

1 MR. BOGLE: Same objection.  
2 THE WITNESS: I still think  
3 it's an overly broad question.  
4 BY MR. EPPICH:  
5 Q. You don't have a response to  
6 my question, sir?  
7 A. I think my response to your  
8 question would be this. My response is:  
9 I believe that greater communication  
10 between DEA and registrants and good  
11 communication is important. I think it's  
12 important in all regulatory functions and  
13 all regulatory agencies.  
14 Whether it will achieve the  
15 objective that you outlaid of preventing  
16 diversion or not, I can't answer to that.  
17 That's outside of the scope of my ability  
18 to answer that. I don't have a crystal  
19 ball. What I can tell you is I think  
20 it's a good thing to have good  
21 communication.  
22 Q. And by greater communication  
23 or good communication, do you mean  
24 frequent communication as well?

Page 269

1 A. I think timely, sufficient,  
2 there's so many factors that go into that  
3 question.  
4 Again I think having the  
5 ability to ask questions and receive  
6 responses, you know, and to talk to one  
7 another, I think is important, period.  
8 I am not going to opine on  
9 how often, how -- frequency or whatever.  
10 I think it depends on facts or  
11 circumstances.  
12 Q. If we can turn to Page 62,  
13 sir.  
14 A. Okay. One minute.  
15 Q. In your report you state  
16 that criticisms by industry --  
17 A. Hold on. Hold on. I'm not  
18 even there yet. Okay. We're on 62. And  
19 where on 62 are you looking, please?  
20 Q. On Page 62, I'm in the first  
21 full paragraph there under your list of  
22 bullet points.  
23 And starting in the second  
24 line at the very end of the line it says,



<p style="text-align: right;">Page 270</p> <p>1 "In the case of McKesson, the narrative 2 about the DEA not providing the company 3 with enough direction to create an 4 effective compliance program persists and 5 has even been adopted by McKesson's board 6 of directors." 7 Do you see that, sir? 8 A. Yes, sir, I do. 9 Q. Now, you've -- you state 10 that criticisms by industry that DEA does 11 not provide sufficient guidance are a 12 narrative. Is that your intent, sir, by 13 using the word "narrative"? 14 MR. BOGLE: Object to form. 15 BY MR. EPPICH: 16 Q. What is your intent with the 17 word "narrative"? What do you mean by 18 that word? 19 A. I think what I meant by the 20 word "narrative" is it's -- that's the 21 version of the way they see the world at 22 the moment. 23 Q. Did you write the word 24 "narrative," or did plaintiffs' counsel</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. Have you reviewed any GAO 2 documents or reports in preparation of 3 your report? 4 A. Well, let's go back and look 5 at the reliance materials and maybe we 6 can find it, but -- 7 Q. You don't recall sitting 8 here today? 9 A. I can't -- as I said, I 10 can't recall -- I don't recall every 11 Bates number off the top of my head. I 12 can go back and look through the reliance 13 materials and try to find it for you to 14 confirm or not. 15 Q. Sitting here today, are you 16 aware the GAO recommended that DEA 17 provide greater guidance to distributors 18 regarding their roles and 19 responsibilities for suspicious order 20 monitoring reporting? 21 MR. BOGLE: Objection to 22 form. 23 THE WITNESS: Again, I'm 24 asking for the document that</p>
<p style="text-align: right;">Page 271</p> <p>1 edit this sentence to include the word 2 "narrative"? 3 A. I wrote the word 4 "narrative." 5 Q. You're aware that the DEA 6 has been repeatedly criticized for 7 failing to provide guidance to industry, 8 correct? 9 MR. BOGLE: Object to form. 10 THE WITNESS: Could you be 11 more specific? 12 BY MR. EPPICH: 13 Q. Well, are you familiar with 14 the government accountability office, the 15 GAO? 16 A. I am familiar with what the 17 GAO is, yes. 18 Q. Are you aware that the GAO 19 issued a report in 2015 that criticized 20 DEA's responsiveness to industry? 21 A. I need to see the document 22 to remember whether I saw it or not. 23 Again, as I've said before, I've seen a 24 lot of documents.</p>	<p style="text-align: right;">Page 273</p> <p>1 you're referring to. If you'd 2 like to show me something and have 3 me comment, I'll be happy to do 4 so. 5 BY MR. EPPICH: 6 Q. Now, earlier today we 7 discussed acting administrator Chuck 8 Rosenberg. Do you remember that 9 discussion? 10 A. Yes, I do remember our 11 discussion. 12 Q. And I believe that you 13 pointed to Dr. Rosenberg's opinions in 14 your report section on the Masters 15 pharmaceutical case, correct? 16 A. I reported -- I pointed to 17 that, in particular, the federal register 18 notice containing those opinions. 19 Q. Are you aware that 20 Mr. Rosenberg testified to Congress on 21 June 22, 2016, as the head of the DEA? 22 A. Is there something in 23 particular that you would like me to look 24 at? I will look at it again.</p>

<p style="text-align: right;">Page 274</p> <p>1 Again, you are asking me  2 about -- I've looked at so many  3 documents, I can't remember all of them  4 off the top of my head.  5 If there's something in  6 particular you'd like me to look at, I'll  7 be happy to do so.  8 Q. And sir, if -- and I  9 appreciate that, I appreciate that.  10 If there's -- if there's  11 testimony from a congressional record or  12 a GAO report that is not identified in  13 your report in Appendix 1 or in the  14 supplemental report, it's fair to say  15 that you have not considered that  16 testimony or that report in forming your  17 opinions as stated in your reports,  18 correct?  19 A. It's fair to say that I  20 don't believe I relied upon it, because I  21 believe I made the reliance list as  22 complete as I could possibly make it.  23 Q. And the plaintiffs' counsel  24 did not provide you with copies of any</p>	<p style="text-align: right;">Page 276</p> <p>1 Q. That would include the  2 Rochester Drug Cooperative deferred  3 prosecution agreement that we saw in your  4 supplemental report?  5 A. Yes, sir.  6 Q. And the U.S. versus C.R.  7 Bard plea agreement that you discuss in  8 your report?  9 A. Yes, sir.  10 Q. And the federal sentencing  11 guidelines that you discuss in your  12 report?  13 A. Yes, sir.  14 Q. Have you always held this  15 opinion, these opinions?  16 A. Have I always held these  17 opinions?  18 Q. Yes, sir.  19 A. Ever since I've been a  20 compliance officer, yes. Again, you use  21 what's available to you to build an  22 effective compliance program. All this  23 material are data points that you can  24 draw from in building an effective</p>
<p style="text-align: right;">Page 275</p> <p>1 GAO reports or any congressional  2 testimony, to your recollection?  3 A. I don't recall. I honestly  4 don't recall at this point.  5 Q. Now, sir, is it your opinion  6 that companies should look to government  7 guidances from the relevant regulatory  8 agencies when designing their compliance  9 programs?  10 A. Yes, they should.  11 Q. That would include the OIG  12 guidances that you discussed in your  13 report?  14 A. Yes.  15 Q. And perhaps even the DOJ  16 updated guidance on evaluating corporate  17 compliance programs that you discussed in  18 your supplemental report?  19 A. Yes.  20 Q. Is it your opinion that  21 companies should look at settlements and  22 precedents when designing their  23 compliance programs?  24 A. Yes.</p>	<p style="text-align: right;">Page 277</p> <p>1 compliance program.  2 Q. Now, you -- you actually  3 held though, the opposite view about  4 these opinions and about the value of  5 looking at guidances from regulatory  6 agencies, settlements, and prior  7 precedents, right?  8 A. I'm not sure what you're  9 talking about, so I -- you're going to  10 have to be more specific, sir.  11 (Document marked for  12 identification as Exhibit  13 Whitelaw-8.)  14 BY MR. EPPICH:  15 Q. Let me introduce as Exhibit  16 Number 8. Exhibit Number 8 is an article  17 entitled "Government Standards Undermine  18 Compliance Efforts in Life Science  19 Companies," by Seth B. Whitelaw dated  20 March 7, 2018. I'll hand you that, sir.  21 A. Yeah, let me see it.  22 Q. You are familiar with this  23 article, sir?  24 A. I am. Is there something in</p>

<p style="text-align: right;">Page 278</p> <p>1 particular that we want to look at in it?</p> <p>2 Q. Yeah. So we -- if we turn</p> <p>3 to Page 2.</p> <p>4 A. Mm-hmm.</p> <p>5 Q. And I'm looking at the</p> <p>6 fourth paragraph down. This was March 7,</p> <p>7 2018. This was roughly six months before</p> <p>8 you were hired by the plaintiffs' counsel</p> <p>9 for your expert role in this case,</p> <p>10 correct?</p> <p>11 A. That would be about right.</p> <p>12 Q. On Page 2 of Exhibit 8,</p> <p>13 we -- we read, "Although the government</p> <p>14 remains steadfast, the companies must</p> <p>15 individually tailor their compliance</p> <p>16 programs to suit each business and</p> <p>17 organization. The OIG, among other</p> <p>18 enforcement bodies, continue" --</p> <p>19 "continues to embrace settlement</p> <p>20 boilerplates and slowly increases the</p> <p>21 burden and complexity for compliance</p> <p>22 officers."</p> <p>23 You previously wrote this</p> <p>24 sentence, didn't you?</p>	<p style="text-align: right;">Page 280</p> <p>1 programs do not reflect the most current</p> <p>2 thinking derived from experts across</p> <p>3 industries."</p> <p>4 You also wrote that,</p> <p>5 correct?</p> <p>6 A. Yes, I did.</p> <p>7 Q. And then finally in the last</p> <p>8 paragraph on this page, and I'm looking</p> <p>9 at the last three lines of that</p> <p>10 paragraph, you wrote, before you were</p> <p>11 hired by the plaintiffs' counsel, that</p> <p>12 "government enforcement agencies must</p> <p>13 change their mindset and their own</p> <p>14 measures of success beyond the number and</p> <p>15 size of settlements."</p> <p>16 You wrote that too, didn't</p> <p>17 you?</p> <p>18 A. Yeah, I did write that.</p> <p>19 Q. Now, these were your</p> <p>20 opinions before you were hired by the</p> <p>21 plaintiffs for this litigation, correct?</p> <p>22 A. Those were my opinions as</p> <p>23 expressed in this article; yes, I wrote</p> <p>24 this article.</p>
<p style="text-align: right;">Page 279</p> <p>1 A. I did.</p> <p>2 Q. And in the next paragraph,</p> <p>3 again before you were hired by the</p> <p>4 plaintiffs in this case, you wrote, "To</p> <p>5 make matters worse, these much touted</p> <p>6 government guidance, settlements, and</p> <p>7 precedents do not reflect leading</p> <p>8 practices."</p> <p>9 You wrote that too, correct?</p> <p>10 A. I did.</p> <p>11 Q. And before you were hired by</p> <p>12 the plaintiffs, in the very last</p> <p>13 paragraph on the -- on the next page.</p> <p>14 Pardon me, on the first paragraph on the</p> <p>15 next page. Four lines down, you write,</p> <p>16 "Therefore, the government provides</p> <p>17 little guidance on how to design and</p> <p>18 maintain a company culture that</p> <p>19 encourages ethical decisionmaking and</p> <p>20 conduct. Ethics is the critical missing</p> <p>21 ingredient in corporate integrity</p> <p>22 agreements. And as a result, these</p> <p>23 documents so often used as the blueprint</p> <p>24 for designing life science compliance</p>	<p style="text-align: right;">Page 281</p> <p>1 Q. And now that you're the</p> <p>2 plaintiffs expert, you're offering the</p> <p>3 opposite opinion, about the usefulness of</p> <p>4 government guidances, settlements and</p> <p>5 other precedents --</p> <p>6 MR. BOGLE: Object to form.</p> <p>7 THE WITNESS: No, I'm not.</p> <p>8 No, I'm not.</p> <p>9 I am not. You are missing</p> <p>10 the point. The point of what I</p> <p>11 was saying was the fact that if</p> <p>12 you look at settlement agreements</p> <p>13 in general, they are tailored to</p> <p>14 specific conduct. If you look at</p> <p>15 the corporate integrity agreements</p> <p>16 in particular is what I was</p> <p>17 speaking to, in life sciences, we</p> <p>18 are talking about specific forms</p> <p>19 of conduct they were attempting to</p> <p>20 address.</p> <p>21 We weren't talking about the</p> <p>22 overall ethics as a culture. And</p> <p>23 there's a whole discussion going</p> <p>24 on in our -- in our business about</p>

<p style="text-align: right;">Page 282</p> <p>1 the role of ethics and the review 2 of just basic compliance and where 3 do those two fit, how do you put 4 those two together, and how do you 5 make a good compliance culture. 6 The conversation I was 7 having, or at least the opinions 8 that I was expressing in here is 9 that my belief was that OIG in 10 particular needed to start 11 thinking about the ethical 12 component as much as they were 13 thinking about the basic 14 compliance component. 15 So that's not inconsistent 16 with the viewpoint that I've 17 expressed in this report. In 18 fact, it is incredibly consistent. 19 BY MR. EPPICH: 20 Q. You cite to this document in 21 your CV, sir? Do you cite to what I've 22 marked -- 23 A. In my CV? 24 Q. -- as Exhibit 9 -- or 8?</p>	<p style="text-align: right;">Page 284</p> <p>1 don't what you to testify what 2 counsel is telling you on the 3 side. I don't think that's 4 appropriate. 5 MR. BOGLE: It's right there 6 on 283. I mean, I would assume 7 you want a complete record. It's 8 right there on 283 in his report. 9 MR. EPPICH: That's fine, 10 Brandon, but let's be above board. 11 MR. BOGLE: I am. 12 MR. EPPICH: Let's go 13 ahead -- let's go ahead and take a 14 break. 15 THE VIDEOGRAPHER: Going off 16 the record at 2:53 p.m. 17 (Short break.) 18 THE VIDEOGRAPHER: We are 19 back on the record at 3:11 p.m. 20 THE WITNESS: Chris, before 21 we go on, I do want to clarify for 22 the record. The publication that 23 we were discussing is in fact on 24 Page 283 of the -- it's in my</p>
<p style="text-align: right;">Page 283</p> <p>1 Excuse me. 2 A. In my CV or in my -- 3 Q. In your CV that's attached 4 to your -- to your report, sir. 5 A. Are you looking for the 6 publications list or are you looking just 7 for the basic CV? I'm trying to 8 understand where you're looking. 9 Q. I'm asking if you identified 10 this particular article in the CV that 11 you've attached to your expert report in 12 this litigation, Exhibit 2? Your CV 13 begins on Page 279. 14 A. If it's not listed here, it 15 was left out by inadvertence. But again 16 I've written a lot over 30 years. I 17 don't remember every single article I've 18 written. I did try to make this as 19 complete and thorough as I could possibly 20 make it for you. 21 MR. EPPICH: We've been 22 going about an hour. 23 THE WITNESS: Wait a minute. 24 MR. EPPICH: I don't -- I</p>	<p style="text-align: right;">Page 285</p> <p>1 publications list. I just didn't 2 see it when I eyeballed it quickly 3 for you. 4 BY MR. EPPICH: 5 Q. Thank you. 6 A. It's there. 7 Q. Thank you, sir. I 8 appreciate that. 9 Let's -- let's turn to Page 10 26 of your report. 11 A. 26? 12 Q. Yes. 13 A. Yes, sir. 14 Q. And this is Section 6.1.2 15 titled "Suspicious Order Monitoring 16 Programs." I'd like to talk to you about 17 some of your opinions in this section. 18 Let's look at the beginning of Paragraph 19 3. 20 And there you state -- 21 A. Is that the one that begins, 22 "As noted"? 23 Q. Yes, sir. 24 A. Okay.</p>

<p style="text-align: right;">Page 286</p> <p>1 Q. And it says, "As noted                  2 throughout this report, the 'know your                  3 customer,' or KYC concept, is critical to                  4 having a successful SOM program."                  5 Do you see that?                  6 A. Yes, sir. I do see the                  7 statement.                  8 Q. Okay. Later in the same                  9 paragraph, your report says -- and I'm                  10 looking about six lines down, all the way                  11 to the end of the sentence. It says, "As                  12 the DEA makes clear, the 'know your                  13 customer' requirement is the basis for                  14 determining whether a customer's                  15 purchases are to be considered legitimate                  16 or diversionary."                  17 Do you see that, sir?                  18 A. I do see that statement,                  19 yes.                  20 Q. And do you agree with that                  21 statement?                  22 A. Yes, sir, I do.                  23 Q. So just because an order                  24 meets the definition of suspicious under</p>	<p style="text-align: right;">Page 288</p> <p>1 BY MR. EPPICH:                  2 Q. And simply because an order                  3 meets the definition of suspicious under                  4 the regulation, that does not mean the                  5 order is going to be diverted, correct?                  6 MR. BOGLE: Object to form.                  7 THE WITNESS: Could you be                  8 more specific? I mean...                  9 BY MR. EPPICH:                  10 Q. Well, my question is simply                  11 an order that meets the definition of                  12 suspicious under the regulation, that                  13 fact alone doesn't mean that that order                  14 will be diverted?                  15 MR. BOGLE: Same objection.                  16 THE WITNESS: Again, I think                  17 it is a possibility, but also                  18 there are multiple possibilities.                  19 So, yes, I would agree with you,                  20 you do need to do further                  21 investigation to determine what is                  22 in fact going on, which was, I                  23 think, the point that I tried to                  24 make throughout my report.</p>
<p style="text-align: right;">Page 287</p> <p>1 the regulation, you'd agree that that                  2 does not mean the order is for an                  3 illegitimate purpose?                  4 MR. BOGLE: Object to form.                  5 THE WITNESS: I would say                  6 that if an order is deemed                  7 suspicious or you think it's                  8 suspicious, it needs further                  9 investigation to determine the                  10 nature of that order, including                  11 all of the above.                  12 BY MR. EPPICH:                  13 Q. And that's because the order                  14 may not be for an illegitimate purpose.                  15 You'd agree with me there?                  16 MR. BOGLE: Objection.                  17 Asked and answered.                  18 THE WITNESS: It's a fairly                  19 broad hypothetical, but yes, that                  20 is a -- one of -- obviously there                  21 are two possibilities here. It's                  22 legitimate or illegitimate. There                  23 are two possibilities. It could                  24 be A or B. Yes.</p>	<p style="text-align: right;">Page 289</p> <p>1 BY MR. EPPICH:                  2 Q. And that's because the                  3 investigation that you do could reveal                  4 that is a legitimate explanation for why                  5 a customer placed an order of unusual                  6 size?                  7 A. There could be a legitimate                  8 explanation. There could be lots of                  9 facts to take into account. Again, it's                  10 fact driven. And as a result of being                  11 fact driven, you need to do a thorough                  12 due diligence and investigation program.                  13 The problem is, is that I didn't see that                  14 happening all that often.                  15 Q. Well, there may be                  16 legitimate explanations for why a                  17 customer places an order that deviates                  18 substantially from normal pattern,                  19 correct?                  20 MR. BOGLE: Object to form.                  21 THE WITNESS: There could be                  22 lots of reasons for that to                  23 happen, both legitimate and                  24 illegitimate. Again, we're back</p>



Page 290

1 to the same point being made, is,  
2 you need to do -- you need to  
3 thoroughly know your customer.  
4 You need to thoroughly need to  
5 know the background of your  
6 customer, and you need to do an  
7 investigation for anything in  
8 flags in your system.  
9 BY MR. EPPICH:  
10 Q. And it's true that there may  
11 be legitimate explanations for why a  
12 customer places an order that deviates  
13 its unusual frequent, correct?  
14 A. Again, we're talking in  
15 hypothetical terms. So hypothetically,  
16 yes.  
17 Q. Now, sir, you're not  
18 offering any opinions in this case that a  
19 particular order to a distributor, a  
20 defendant in this case, was suspicious?  
21 MR. BOGLE: Object to form.  
22 THE WITNESS: Could you be  
23 more specific. When you say I'm  
24 not offering an opinion on

Page 291

1 suspicious -- I don't understand.  
2 BY MR. EPPICH:  
3 Q. Have you reviewed any of the  
4 orders placed to any of the distributors  
5 or manufacturers in this case?  
6 A. Yes, I have.  
7 Q. Are you offering any  
8 opinions in this case about the  
9 legitimacy or the illegitimacy of those  
10 orders?  
11 MR. BOGLE: Object to form.  
12 THE WITNESS: I'm offering  
13 opinions as to whether or not,  
14 when those orders, for whatever  
15 reason were being examined, the  
16 quality of the data that was being  
17 generated to determine whether or  
18 not -- I'm a compliance -- I'm a  
19 processes guys, processes and  
20 procedures. I'm looking at your  
21 processes and procedures. I'm  
22 looking at what your documentation  
23 says in the record. I'm making  
24 opinions about the adequacy of

Page 292

1 that documentation and the  
2 adequacy of that process and  
3 whether or not you followed it or  
4 not.  
5 BY MR. EPPICH:  
6 Q. Right. So I'm just trying  
7 to get a sense for the scope of your  
8 opinions.  
9 Your opinions are about the  
10 processes and procedures. They are not  
11 about whether a specific order to  
12 McKesson for example, that happened on  
13 September 7th of 2004, is a suspicious  
14 order or not, correct?  
15 A. I am --  
16 MR. BOGLE: Object to form.  
17 Go ahead. Sorry.  
18 THE WITNESS: I am giving  
19 you an opinion about whether or  
20 not for that specific order, if  
21 that's one of the orders that I  
22 looked at, whether or not there's  
23 adequate information in the file  
24 whether McKesson followed the

Page 293

1 procedures that they said that  
2 they were going to be doing at  
3 that particular point in time. In  
4 fact, did they have a record, you  
5 have a record to actually make a  
6 judgment one way or the other.  
7 Am I questioning your  
8 individual judgment? I'm  
9 questioning the adequacy of the  
10 record.  
11 BY MR. EPPICH:  
12 Q. And any -- any of your  
13 opinions on such orders, we would find  
14 those in your report, correct?  
15 A. I believe you would. Again,  
16 I'd have to review every section of the  
17 order. But we can go through the entire  
18 report if you'd like.  
19 Q. Have you looked at any  
20 defendants' transactional data in this  
21 case?  
22 A. Could you define what you  
23 mean by transactional data?  
24 Q. Sales data, order data, any

<p style="text-align: right;">Page 294</p> <p>1 transactional data, some of the ARCOS  2 data. Have you reviewed any of that?  3 A. Yes, I've reviewed some of  4 it. I can't say exactly all the data  5 that I've looked at. I have looked at a  6 lot of data.  7 Q. Let's turn to Page 33 of  8 your report. Page 33 in the Section 6.4,  9 "Monitoring, Auditing &amp; Investigations."  10 And on Page 33 I'm looking  11 at the second full paragraph. And  12 I'll -- and I'll read the sentence. It  13 says, "Utilized correctly the  14 establishment of threshold" --  15 "thresholds, a cap on the amount of  16 controlled substances a customer can  17 order in a set period is an effective way  18 to identify, but not confirm suspicious  19 orders."  20 Did I read that correctly?  21 A. Yes, I think you did.  22 Q. Do you agree with that  23 statement?  24 A. Yes, sir, I do.</p>	<p style="text-align: right;">Page 296</p> <p>1 the -- the rules, regulations and  2 guidance, et cetera, from DEA. My  3 conversations with Mr. Rafalski, et  4 cetera.  5 Q. But you don't have any  6 experience setting thresholds for opioid  7 products, do you?  8 A. No, I have no experience  9 setting opioid thresholds products. But  10 I do have experience in setting  11 thresholds for noncontrolled substances  12 samples.  13 Again, it's -- what criteria  14 do you need to look at to make sense,  15 what's the level that makes sense, and  16 then set the number.  17 But again, I'm also not a  18 statistician. I would leave the actual  19 work to that to a statistician. But yes,  20 I know how generally how you put a  21 threshold together and use it.  22 Q. Let's go ahead and look at  23 the last two sentences on this Page 33.  24 They are -- they start on the second</p>
<p style="text-align: right;">Page 295</p> <p>1 Q. Thresholds are a cap on the  2 amount of controlled substances that a  3 customer may order in a set time period;  4 is that correct?  5 A. That's how I'm defining it,  6 yes.  7 Q. And you'd agree that  8 establishing thresholds is an effective  9 way for a registrant to identify  10 suspicious orders?  11 A. I say I would qualify that  12 to say to you, again the point I was  13 making is it's a way to start the  14 process. It's a way to create a flag for  15 you to then to do further investigation  16 and further follow-up. It's not the only  17 way, and it's not in and of itself  18 sufficient.  19 Q. What -- what basis do you  20 have for -- for the opinions that you  21 express in this particular sentence, sir?  22 A. I have, again, my work,  23 30 years as a compliance expert. My work  24 in working on this case. My reading of</p>	<p style="text-align: right;">Page 297</p> <p>1 sentence of that last full paragraph.  2 And it reads, "However, if the  3 investigation determines that there is a  4 risk of diversion, the order must not be  5 filled and the company should contemplate  6 other appropriate steps for handling  7 future shipment requests. Those steps  8 include refusing to ship any more  9 products to the customer, requiring the  10 customer to provide independent assurance  11 that a diversion situation is not  12 present, or terminating the customer  13 altogether."  14 Do you see that, sir?  15 A. Yes, sir, I do.  16 Q. And do you agree with these  17 statements?  18 A. Yes, sir, I do.  19 Q. When the company investigate  20 an order flagged as suspicious and finds  21 that it is a legitimate order, the order  22 can be shipped, correct?  23 A. If the company investigates  24 the order and finds that the order in</p>

<p style="text-align: right;">Page 298</p> <p>1 their mind, based on their investigation  2 and due diligence, is not suspicious,  3 then -- and -- and cleared all the red  4 flags that got it to flag in the first  5 place and have a legitimate rationale  6 behind it, yes, they can ship the order.  7 Q. And after an order is  8 investigated and found not to be  9 suspicious, an order that follows that  10 order is not necessarily suspicious,  11 correct?  12 MR. BOGLE: Object to form.  13 THE WITNESS: I'm not sure.  14 Could you be a bit more specific?  15 BY MR. EPPICH:  16 Q. Let me re-ask the question.  17 After an order is  18 investigated and found not to be  19 suspicious, an order that follows that  20 first order that was flagged is not  21 necessarily suspicious, as long as that  22 order is within the threshold limits set  23 by the program, you'd agree with that,  24 correct?</p>	<p style="text-align: right;">Page 300</p> <p>1 there -- what is the definition of a  2 suspicious order?  3 A. I guess we can look. You  4 gave me the regulation earlier. Would  5 you like me to read the regulation back?  6 Q. Sure.  7 A. Okay. I will.  8 Q. It's Exhibit 4, sir.  9 A. I'm finding it. It says  10 "The registrant shall design and operate  11 a system to disclose to the registrant  12 suspicious orders of controlled  13 substances. The registrant shall inform  14 the field division office of the  15 administration of his or her suspicious  16 orders when discovered by the registrant.  17 Suspicious orders include orders of  18 unusual size, orders deviating  19 substantially from a normal pattern, and  20 orders of unusual frequency."  21 Q. Sir, do you believe the  22 language defining a suspicious order in  23 Section B of 1301.74 is clear?  24 A. Yes, I do believe it's</p>
<p style="text-align: right;">Page 299</p> <p>1 MR. BOGLE: Object to form.  2 Improper hypothetical.  3 THE WITNESS: It's too broad  4 a hypothetical. There are other  5 factors that can be -- again,  6 be -- be taken into account.  7 Thresholds are not the only way to  8 determine if an order is  9 suspicious.  10 BY MR. EPPICH:  11 Q. Let me ask you a different  12 question.  13 After an order is  14 investigated and found -- let me strike  15 that.  16 If we call the order that  17 exceeds the threshold -- let me strike  18 that.  19 I'd like to talk to you  20 about the definition of a suspicious  21 order, sir.  22 A. Are we looking at someplace  23 in particular in my report, sir?  24 Q. Well, first -- and we'll get</p>	<p style="text-align: right;">Page 301</p> <p>1 clear.  2 Q. Do you believe the phrase  3 "order of unusual size" in the regulation  4 is clear?  5 A. I believe you have to put it  6 in the context of the customer, which I  7 think is what the DEA has been telling  8 you all along, which is you have to know  9 your customer. So if you put it into  10 context, yes, I think unusual size is  11 clear. Again, it's tailored to the  12 individual customer.  13 Q. You'd agree the regulation  14 does not define unusual size, correct?  15 A. I would agree that there is  16 no precise definition of what unusual  17 size means in the regulation.  18 Q. What is an order of unusual  19 size?  20 A. I think -- I'm not sure what  21 you're asking me. I mean, that's such an  22 open-ended question.  23 Q. I'm asking if you can give  24 me an example of an order of unusual size</p>

Page 302

1 within the definition of suspicious order  
 2 found in Section 1301.74(b).  
 3 A. Again, because we have to  
 4 talk about customer in context and  
 5 everything else, I'm not sure that I can  
 6 give you what you're asking for. You're  
 7 looking for -- it sounds like that you're  
 8 looking for a precise numerical value.  
 9 Is that what you're looking for? I don't  
 10 understand.  
 11 Q. Sitting here today, are you  
 12 able to provide me with the meaning of,  
 13 and I quote, "order of unusual size" as  
 14 found in the regulation Section  
 15 1301.74(b)?  
 16 A. As I think we just discussed  
 17 1301.74(b) doesn't have a precise  
 18 definition of what an order of unusual  
 19 size is.  
 20 Q. Sitting here today, you  
 21 personally do not have a definition of  
 22 what an order of unusual size is?  
 23 MR. BOGLE: Object to form.  
 24 Asked and answered.

Page 303

1 THE WITNESS: Again, I think  
 2 it's such an open-ended question  
 3 that has -- that needs necessary  
 4 context around it, no, I do not  
 5 have a hypothetical definition for  
 6 you.  
 7 BY MR. EPPICH:  
 8 Q. Do you believe that the  
 9 phrase "order deviating substantially  
 10 from a normal pattern" in the regulation  
 11 is clear?  
 12 A. Again, yes, I think it's  
 13 clear if you set it in the context of a  
 14 particular customer. I think once again  
 15 it has to be set into customer context.  
 16 Q. You agree that the  
 17 regulation does not define "deviating  
 18 substantially"?  
 19 A. I do not see a definition  
 20 for "deviating substantially" in the  
 21 regulations.  
 22 Q. Well, in your opinion, sir,  
 23 what is an order deviating substantially  
 24 from a normal pattern?

Page 304

1 A. I'm going to give you the  
 2 same answer that I gave to you on unusual  
 3 size. It's all context driven. It's  
 4 impossible to give you a blanket  
 5 one-size-fits-all definition. We'd have  
 6 to look at it customer by customer, fact  
 7 pattern by fact pattern.  
 8 Q. Do you believe the phrase  
 9 "order of unusual frequency" in the  
 10 regulation is clear?  
 11 A. Again, the answer is yes, I  
 12 believe it's clear if you set it in the  
 13 appropriate context with the appropriate  
 14 customer.  
 15 Q. The regulation does not  
 16 define unusual frequency?  
 17 A. I do not see a definition of  
 18 unusual frequency in the regulation.  
 19 Q. And in your opinion, sir,  
 20 what is an order of unusual frequency?  
 21 A. Again, we're going to going  
 22 back to the same one. I can't give you a  
 23 blanket definition of unusual frequency,  
 24 because it is fact dependent, fact driven

Page 305

1 and depends on the facts and  
 2 circumstances of your customer.  
 3 Q. If we can turn to Page 117  
 4 of your report. Sir, I'm looking at the  
 5 first two full paragraphs of this page.  
 6 I'm just going to read you what you wrote  
 7 in the second paragraph about Cardinal's  
 8 process for identifying suspicious  
 9 orders.  
 10 You say -- and this is the  
 11 first sentence of that second full  
 12 paragraph.  
 13 "Cardinal's process,  
 14 however, does not define significantly  
 15 larger, significantly more frequent, or  
 16 significant deviation. Therefore, it is  
 17 unclear what significant means in this  
 18 context."  
 19 Do you see that, sir?  
 20 A. I do.  
 21 Q. How is unusual size, as  
 22 written in the regulation, clear, but the  
 23 use of "significantly larger" in  
 24 Cardinal's policy unclear?

<p style="text-align: right;">Page 306</p> <p>1 A. Well, the regulation was  2 drafted for every registrant and it was  3 drafted for every customer out there. So  4 it is a very broad standard.  5 In the case of Cardinal,  6 Cardinal is supposed to know their  7 customers and should be able to say what  8 does that mean in context of Cardinal's  9 customers and provide at least some level  10 of granularity and criteria around it.  11 Q. Sir, how is deviating  12 substantially as written in the  13 suspicious order regulation clear, but  14 Cardinal's use of significant deviation  15 unclear?  16 A. I think we're going to have  17 the same conversation. But we'll go back  18 to it, which is, again, we're talking  19 about a regulation that is written for  20 all registrants, all customers. In this  21 case we're talking about Cardinal and  22 Cardinal knowing Cardinal's customers and  23 being able to make some judgments based  24 on what they know about their customers.</p>	<p style="text-align: right;">Page 308</p> <p>1 Ecosystem," and in the last paragraph on  2 Page 48 you write, "Therefore, because  3 the closed system is an ecosystem, any  4 examination should look at the operation  5 of the full ecosystem as well as the  6 individual parts. Euclid Family  7 Pharmacy, and CVS Stores 3322 and 4800  8 provide excellent examples to do so."  9 Do you see that, sir?  10 A. I do.  11 Q. What is your source for the  12 concept of a, quote, integrated  13 ecosystem?  14 A. I think it follows what  15 we're talking about, what a closed loop  16 system. Everybody has a role to play in  17 the closed loop system. And the point  18 that I was making here around the  19 ecosystem is the fact that it is possible  20 to work with multiple players. And if  21 you want to look at the "know your  22 customer" concept, you need to look at  23 the entire -- you just don't look at  24 yourself in isolation. You look at all</p>
<p style="text-align: right;">Page 307</p> <p>1 Q. And finally, sir, how is  2 unusual frequency as written in the  3 suspicious order regulation clear but  4 significantly more frequently as used in  5 Cardinal's policy unclear?  6 A. Well, again, back to the  7 original answer. We'll just do it in a  8 slightly different context, we're talking  9 about a regulation that's driven and  10 written for all registrants and all  11 customers. And again, in this particular  12 case we are talking about a subset,  13 Cardinal's customers. Cardinal having  14 knowledge of Cardinal's customers should  15 be able to define what that means, based  16 on Cardinal's customers.  17 Q. Let's turn to Page 48 of  18 your report.  19 A. Page 48, you said? Is that  20 correct, Chris?  21 Q. Yes, sir. Page 48.  22 A. Okay. I'm here.  23 Q. On Page 48, in Section 8.4,  24 which you've titled "An Integrated</p>	<p style="text-align: right;">Page 309</p> <p>1 the facts and circumstances and totality  2 that you have.  3 Q. And so is it your opinion,  4 sir, that the closed system of drug  5 distribution is an example of an  6 integrated ecosystem?  7 A. I believe the closed loop  8 system is an ecosystem in and of itself,  9 yes.  10 Q. And that's based on your  11 years of experience and knowledge in this  12 field, sir?  13 A. It's based on my experience  14 and knowledge in this field, yes, sir.  15 Q. Now, you offer opinions on  16 three stores for your discussion on the  17 integrated ecosystem, Euclid Family  18 Pharmacy, CVS Store 3322 and CVS Store  19 4800. Did you identify these stores  20 yourself?  21 A. I'm not sure I'm asking -- I  22 understand. Did I ask -- did I use these  23 stores myself, yes. I asked for, again,  24 from counsel, to provide me with examples</p>



Page 310

1 of various pharmacies and stores, showing  
 2 due diligence, showing high level of  
 3 prescriptions in those various areas for  
 4 Cuyahoga and Summit Counties, and I read  
 5 the files that I had and worked from  
 6 there.  
 7 Q. And plaintiffs' counsel  
 8 provided you with the identifications and  
 9 the files relating to the Euclid Family  
 10 Pharmacy and CVS Store 3322 and CVS Store  
 11 4800?  
 12 A. Upon my request, yes, they  
 13 did.  
 14 Q. Do you intend to offer  
 15 opinions on any other pharmacies as part  
 16 of the integrated ecosystem?  
 17 MR. BOGLE: Object to form.  
 18 THE WITNESS: I'm not  
 19 sure -- again, I'm not sure I  
 20 understand your point.  
 21 BY MR. EPPICH:  
 22 Q. That's a fair point. I  
 23 think the question was -- was a little  
 24 rough there. Let me ask it a different

Page 311

1 way.  
 2 In your section on an  
 3 integrated ecosystem, you've identified  
 4 three pharmacies, the Euclid Family  
 5 Pharmacy, CVS Store 3322 and CVS Store  
 6 4800.  
 7 Sitting here today, do you  
 8 intend to offer opinions about any other  
 9 pharmacies as part of your discussion on  
 10 an integrated ecosystem?  
 11 A. Assuming facts --  
 12 MR. BOGLE: Object to form.  
 13 THE WITNESS: Assuming facts  
 14 and circumstances don't change,  
 15 no. But again, these three  
 16 pharmacies were listed as  
 17 examples. Similar to the way,  
 18 Chris, that you do an audit.  
 19 You know, when you do an  
 20 audit and you are looking at  
 21 documents and you see an issue,  
 22 you highlight the issue using the  
 23 document -- using examples to  
 24 support it. You don't -- it's not

Page 312

1 an exhaustive list. It's not  
 2 every pharmacy. It's enough to  
 3 show that there is an issue. This  
 4 was what I did in this particular  
 5 account.  
 6 BY MR. EPPICH:  
 7 Q. Have you considered any  
 8 other pharmacies as part of your analysis  
 9 of an integrated ecosystem sitting here  
 10 today?  
 11 A. I'm sure I did, because  
 12 obviously I got to these three. So I  
 13 know I looked at others. Can I tell you  
 14 which ones they were? No, I can't. Not  
 15 at this point.  
 16 Q. Let's turn to Page 49 of  
 17 your report. And here you discuss -- you  
 18 discuss the Euclid Family Pharmacy.  
 19 Now, specifically how did  
 20 you go about identifying the Euclid  
 21 Family Pharmacy as part of the integrated  
 22 ecosystem?  
 23 MR. BOGLE: Objection.  
 24 Asked and answered.

Page 313

1 THE WITNESS: Again, I  
 2 looked at pharmacies that were  
 3 provided -- that were working in  
 4 Summit and Cuyahoga County. They  
 5 happened to have high patterns of  
 6 opioids throughout the period --  
 7 the review period in time.  
 8 I started reading the  
 9 record, and in the case of Euclid  
 10 and the others that were there, I  
 11 was noticing what we are talking  
 12 about, a situation, again, where  
 13 we have multiple distribution --  
 14 distributors involved.  
 15 It's not just a single  
 16 distributor. It's not just a  
 17 single entity registrant involved.  
 18 There are multiple registrants.  
 19 BY MR. EPPICH:  
 20 Q. Did you evaluate other  
 21 pharmacies, aside from these three, when  
 22 you were forming opinions about an  
 23 integrated ecosystem?  
 24 A. As I thought I answered

Page 314

1 before, I screened through -- I screened  
2 a lot of pharmacies. I looked at a lot  
3 of different pharmacies, and some in  
4 Cuyahoga County.

5 Q. And do you recall any of the  
6 pharmacies' names that you screened and  
7 did not identify here in Section 8.4?

8 A. As I said before, I do not  
9 recall which individual pharmacies I  
10 looked at. I can't -- I've looked at a  
11 lot of records and a lot of pharmacies,  
12 so I can't give you an honest -- you  
13 know, I can't honestly -- I'd be  
14 guessing, and I don't guess.

15 Q. Now, sir, on Page 50 of your  
16 report you rely on McKesson's regulatory  
17 investigative report on Euclid Pharmacy,  
18 correct? And specifically I'm looking at  
19 Footnote 174.

20 A. Yes, I've seen that  
21 document, yes.

22 Q. Did you review the entire  
23 file?

24 A. Yes, sir, I did.

Page 316

Page 315

1 Q. Your report also discusses a

2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

Page 317

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]

19 That's what I opined on.

20 Q. Did you consider the Ohio  
21 Bureau of Workers' Compensation  
22 requirements in forming any of the  
23 opinions in your report, sir?

24 A. Again, they were not germane

<p style="text-align: right;">Page 318</p> <p>1 to my report, so the answer is no.</p> <p>2 Q. Are you aware that Euclid</p> <p>3 Family Pharmacy still has an active DEA</p> <p>4 registration?</p> <p>5 A. I haven't checked their DEA</p> <p>6 registration anytime recently. So I --</p> <p>7 I'm unaware of that.</p> <p>8 Q. Have you ever checked the</p> <p>9 Euclid Family Pharmacy registration?</p> <p>10 A. No, I have not independently</p> <p>11 checked the Euclid Family Pharmacy's DEA</p> <p>12 registration. I have read the DEA -- I</p> <p>13 have read McKesson's files which show</p> <p>14 licenses in them, but, yes.</p> <p>15 But beyond that, no.</p> <p>16 Q. Are you aware if the Euclid</p> <p>17 Family Pharmacy is still registered by</p> <p>18 the Ohio Board of Pharmacy?</p> <p>19 A. No, I am not aware. Again,</p> <p>20 it wasn't germane to this discussion.</p> <p>21 Q. You didn't check the</p> <p>22 registration records of the Ohio Board of</p> <p>23 Pharmacy?</p> <p>24 A. Again, it wasn't germane to</p>	<p style="text-align: right;">Page 320</p> <p>1 integrated ecosystem?</p> <p>2 A. I used the same methodology</p> <p>3 we used before, but we can go over it</p> <p>4 again if you'd like.</p> <p>5 I asked counsel for a list</p> <p>6 of stores from Cuyahoga and Summit</p> <p>7 Counties that had large volumes of</p> <p>8 opioids, and then read the files and</p> <p>9 selected the sample.</p> <p>10 Q. Sir, do you intend to offer</p> <p>11 any opinions about CVS Store 3322 other</p> <p>12 than those set forth in your report?</p> <p>13 A. Unless set facts and</p> <p>14 circumstances change and new information</p> <p>15 becomes available, I do not have any</p> <p>16 intention at this time.</p> <p>17 Q. On Page 52 of your report,</p> <p>18 you discuss CVS Store 4800 in Section C,</p> <p>19 correct?</p> <p>20 A. I do.</p> <p>21 Q. Do you intend to offer any</p> <p>22 opinions about CVS Store 4800 other than</p> <p>23 those set forth in your report?</p> <p>24 A. Again, unless there is new</p>
<p style="text-align: right;">Page 319</p> <p>1 the point and the discussion we were</p> <p>2 having here, no.</p> <p>3 Q. Do you intend to offer any</p> <p>4 opinions about Euclid Family Pharmacy</p> <p>5 other than those set forth in your</p> <p>6 report?</p> <p>7 A. Unless we have new facts and</p> <p>8 circumstances, I think the point -- we</p> <p>9 made the point about the store and what</p> <p>10 we were trying -- what I was trying to</p> <p>11 show.</p> <p>12 Q. Is the answer to my question</p> <p>13 no?</p> <p>14 A. My answer to the question is</p> <p>15 unless the facts and circumstances</p> <p>16 change, I do not have any intention at</p> <p>17 this moment in time of adding anything</p> <p>18 new.</p> <p>19 Q. If we can turn back to</p> <p>20 Page 51 of your report. Under Section B,</p> <p>21 CVS Store 3322.</p> <p>22 A. Yes.</p> <p>23 Q. And here -- how did you</p> <p>24 identify CVS 3322 as part of your</p>	<p style="text-align: right;">Page 321</p> <p>1 information that comes to light and based</p> <p>2 on facts and circumstances, I have no</p> <p>3 present intention of adding things to</p> <p>4 this report.</p> <p>5 Q. If we could continue, on</p> <p>6 Page 53, it begins, Section 9 on McKesson</p> <p>7 Corporation specifically. And if you</p> <p>8 wouldn't mind turning to Page 55.</p> <p>9 A. 55, yes, sir.</p> <p>10 Q. This is under Subsection</p> <p>11 9.3, "Impact."</p> <p>12 A. Yes.</p> <p>13 Q. Do you see that, sir?</p> <p>14 A. I do.</p> <p>15 Q. I'd like to read from the</p> <p>16 first full paragraph on Page 55 which</p> <p>17 states -- and pardon me, it's -- it's the</p> <p>18 first full paragraph there. It starts,</p> <p>19 "As a result, various retail pharmacies</p> <p>20 obtained high levels of opioids with</p> <p>21 little or no investigation or</p> <p>22 interrogation. Below are a few</p> <p>23 illustrative examples."</p> <p>24 Then you have a discussion</p>

<p style="text-align: right;">Page 322</p> <p>1 of Acme 30, correct?</p> <p>2 A. I do.</p> <p>3 Q. Now, Acme 30 is the only</p> <p>4 pharmacy in either Summit or Cuyahoga</p> <p>5 County that you offer an opinion on</p> <p>6 impact for, correct?</p> <p>7 A. Let me read the report.</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: Could you be</p> <p>10 more specific?</p> <p>11 BY MR. EPPICH:</p> <p>12 Q. Is Acme 30 located in Summit</p> <p>13 County or Cuyahoga County, Ohio, sir?</p> <p>14 A. According to my report here</p> <p>15 it says Summit County, Ohio.</p> <p>16 Q. Is the Franklin Pharmacy</p> <p>17 located in Summit or Cuyahoga County?</p> <p>18 And the Franklin Pharmacy, sir, is on</p> <p>19 Page 57.</p> <p>20 A. Franklin Pharmacy is located</p> <p>21 in Warren, which is in the county</p> <p>22 adjacent to Summit and Cuyahoga County.</p> <p>23 Q. So Franklin Pharmacy, sir,</p> <p>24 is not in Summit or Cuyahoga County?</p>	<p style="text-align: right;">Page 324</p> <p>1 A. Once more, again, unless new</p> <p>2 information becomes available that would</p> <p>3 cause me to reconsider, I have no</p> <p>4 intentions of amending the report at this</p> <p>5 point in time.</p> <p>6 Q. Let's turn to Page 57 of</p> <p>7 your report, sir. Are you aware that</p> <p>8 McKesson terminated the Franklin Pharmacy</p> <p>9 as a customer?</p> <p>10 A. I'm going to read the</p> <p>11 section. I'm aware that there was</p> <p>12 recommendation for termination, yes.</p> <p>13 Q. Are you aware that the</p> <p>14 Franklin Pharmacy still possesses a valid</p> <p>15 DEA registration?</p> <p>16 A. I have not checked the</p> <p>17 Franklin Pharmacy's current DEA</p> <p>18 registration.</p> <p>19 Q. Are you aware that the</p> <p>20 Franklin pharmacy still possesses a valid</p> <p>21 registration from the Ohio Board of</p> <p>22 Pharmacy?</p> <p>23 A. I haven't checked Franklin</p> <p>24 Pharmacy's current Ohio Board of Pharmacy</p>
<p style="text-align: right;">Page 323</p> <p>1 A. That is correct.</p> <p>2 Q. On Page 58, there's</p> <p>3 identified a Martella's Pharmacy.</p> <p>4 Do you see that, sir?</p> <p>5 A. I do.</p> <p>6 Q. Is the Martella's Pharmacy</p> <p>7 located in Summit or Cuyahoga County,</p> <p>8 Ohio?</p> <p>9 A. No.</p> <p>10 Q. Do you intend to offer any</p> <p>11 other opinions about any other McKesson</p> <p>12 customers in Summit County or Cuyahoga</p> <p>13 County other than Acme 30 and Euclid</p> <p>14 Family Pharmacy?</p> <p>15 A. Again, I have no plans</p> <p>16 unless facts and circumstances and new</p> <p>17 information becomes available, I reserve</p> <p>18 the right to amend my report. But other</p> <p>19 than that, I have no present plans to</p> <p>20 amend it.</p> <p>21 Q. Do you intend to offer any</p> <p>22 opinions -- any other opinions about Acme</p> <p>23 30 other than those set forth in your</p> <p>24 report on Pages 55 and 56?</p>	<p style="text-align: right;">Page 325</p> <p>1 license status.</p> <p>2 Q. Do you intend to offer any</p> <p>3 opinions about the Franklin Pharmacy</p> <p>4 other than those set forth in your</p> <p>5 report?</p> <p>6 A. At the present time I have</p> <p>7 no intentions unless new information</p> <p>8 becomes available of amending this</p> <p>9 section on this -- in regards to Franklin</p> <p>10 Pharmacy.</p> <p>11 Q. If we can turn to Page 58,</p> <p>12 sir. And your discussion of Martella's</p> <p>13 Pharmacy.</p> <p>14 A. I see it.</p> <p>15 Q. Now, Martella's Pharmacy is</p> <p>16 in Johnstown, Pennsylvania, correct?</p> <p>17 A. Yes, that is correct,</p> <p>18 according to my report.</p> <p>19 Q. And Johnstown, Pennsylvania</p> <p>20 is approximately 200 miles from</p> <p>21 Cleveland, right?</p> <p>22 A. I have no idea. I have not</p> <p>23 measured the distance between Johnstown</p> <p>24 and Cleveland.</p>

<p style="text-align: right;">Page 326</p> <p>1 Q. Do you intend to offer any  2 opinions about Martella's Pharmacy other  3 than those set forth in your report?  4 A. Again, unless there are new  5 facts or circumstances that come to  6 light, I have no present intention of  7 amending the report.  8 Q. If we can turn to Page 68 of  9 your report.  10 I'm looking at  11 Section 9.4.4, "McKesson failed to  12 resource the controlled substance program  13 appropriately."  14 A. Yeah, I see -- I see the  15 section where you're talking.  16 Q. I want to look at the last  17 sentence on Page 68. There you write,  18 about four lines from the bottom of that  19 paragraph, "Analyzing those numbers  20 specifically for controlled substances  21 provides the additional insight that even  22 after the head count expansion that began  23 in 2012, McKesson still only had one  24 controlled substances regulatory affairs</p>	<p style="text-align: right;">Page 328</p> <p>1 controlled substances from McKesson,  2 correct?  3 A. I'm sorry. I'm not sure I  4 understand your question.  5 Q. Your analysis assumes that  6 every McKesson customer that sells  7 controlled substances purchased those  8 controlled substances from McKesson,  9 correct?  10 A. I'm assuming -- I was  11 talking only in terms of McKesson  12 customers period. So I'm not sure I'm  13 understanding the distinction that you're  14 trying to make.  15 Q. Sir, you're aware that a  16 pharmacy customer of McKesson's can also  17 be the pharmacy customer of a second  18 distributor, correct?  19 A. There is that potential,  20 yes.  21 Q. And it's true that  22 McKesson's pharmacy customer could be  23 purchasing its controlled substances from  24 that second supplier, correct?</p>
<p style="text-align: right;">Page 327</p> <p>1 person for each distribution center and  2 redistribution hub who oversaw  3 approximately 1,240 controlled substances  4 orders per night involving an average 833  5 customers."  6 Do you see that, sir?  7 A. Yes, I do.  8 Q. And you state in the  9 footnote of that sentence, that your  10 analysis is based on the assumption every  11 McKesson customer sells controlled  12 substances in 2014.  13 Did I understand that  14 correctly?  15 A. You did.  16 Q. Your analysis would be  17 different if not every McKesson customer  18 sold controlled substances in 2014,  19 correct?  20 A. Yes. There would be a  21 different number.  22 Q. Your analysis here also  23 assumes that every McKesson customer that  24 sells controlled substances buys those</p>	<p style="text-align: right;">Page 329</p> <p>1 A. That is a possibility.  2 Q. And so sir, your analysis  3 assumes that McKesson's customers that  4 sell controlled substances buys those  5 controlled substances from McKesson and  6 not some other distributor, correct?  7 A. That's correct.  8 Q. And so your analysis would  9 change if McKesson's customer who sells  10 controlled substances actually bought  11 their controlled substances from a  12 secondary supplier, correct?  13 A. The numbers would  14 potentially change, yes.  15 Q. If we can turn to Page 70.  16 The first paragraph states -- and I'm at  17 the very top of the page, sir.  18 A. Hang on a second. I'm  19 trying to get there.  20 Q. It says, "On top of  21 reviewing suspicious orders, the  22 controlled substances staff members are  23 each responsible for knowing  24 approximately 833 customers, including</p>



<p style="text-align: right;">Page 330</p> <p>1 performing onboarding and active  2 monitoring the information that could  3 affect ordering patterns, e.g., regions  4 served, county population, sales  5 representative visit information, et  6 cetera."  7 Do you see that, sir?  8 A. I do.  9 Q. And by 2017 -- you write,  10 "By 2017, that number had climbed to 909  11 customers per staff member."  12 Did I -- did I read that  13 correctly?  14 A. Yes, you did.  15 Q. And in Footnote 298 on that  16 same page, you state that this analysis  17 assumes every McKesson customer sells  18 controlled substances.  19 So, again, your analysis  20 here also assumes that every McKesson  21 customer buys its controlled substances  22 from McKesson, correct?  23 A. Yes. That's what -- that's  24 what it says.</p>	<p style="text-align: right;">Page 332</p> <p>1 investigation. It's a lot of work.  2 Let's just be honest. It's a lot of  3 work.  4 MR. EPPICH: I'll move to  5 strike everything after "the  6 numbers would be different."  7 BY MR. EPPICH:  8 Q. Sir, your analysis would be  9 different if not every McKesson customer  10 sold controlled substances in 2014,  11 correct?  12 A. The underlying analysis that  13 there's too much work to be done by too  14 few people that is in my report would  15 still be there, whether the exact number  16 would be 833 or 750, that might change,  17 but the point I'm making that it was  18 underresourced is still a valid point.  19 Q. And, sir, just to answer my  20 question. Your analysis would be  21 different if not every McKesson customer  22 sold controlled substances in 2014, yes  23 or no?  24 MR. BOGLE: Objection.</p>
<p style="text-align: right;">Page 331</p> <p>1 Q. And your analysis -- and  2 your analysis also assumes that every  3 McKesson customer that sells controlled  4 substances buys those controlled  5 substances from McKesson?  6 A. Yes.  7 Q. Now, your analysis would be  8 different if not every McKesson customer  9 that sells controlled substances bought  10 those controlled substances from McKesson  11 or at all, correct?  12 A. The numbers would be  13 different. I think the point that I'm  14 trying to make here is based on the best  15 available evidence I have, if you try to  16 figure out what the workload facing the  17 McKesson staff were, they were under --  18 they were underresourced.  19 Because it's not just  20 looking at all suspicious orders. It's  21 all the other things that go along,  22 training, education, looking and knowing  23 your customers, doing the profiles,  24 keeping them up-to-date, doing the</p>	<p style="text-align: right;">Page 333</p> <p>1 Asked and answered. You don't  2 have to answer it yes or no if  3 that's not the way you can answer  4 the question.  5 MR. EPPICH: This is a yes  6 or no question.  7 MR. BOGLE: That's not for  8 you to decide.  9 THE WITNESS: I do not think  10 it's a yes or no answer.  11 Again, my analysis holds  12 that the staff are understaffed  13 and overworked for what was being  14 asked.  15 And yes, the underlying root  16 number might, in fact, change.  17 BY MR. EPPICH:  18 Q. Let's go ahead and turn back  19 to Page 69. And on Page 69, the last two  20 sentences at the end of 69 of your report  21 say, and this is four lines from the  22 bottom of that paragraph, sir: "Working  23 with McKesson's data disclosed to the  24 U.S. Attorney's Office and others, at the</p>

<p style="text-align: right;">Page 334</p> <p>1 2014 staffing level of 30 FTEs for SOM          2 and assuming every team member is doing          3 some suspicious order reviews, each team          4 member had to review approximately 18 new          5 suspicious orders per day. By 2017, that          6 number drops to approximately nine per          7 day per staff member, which is still a          8 significant workload."          9 Do you see that, sir?          10 A. I do.          11 Q. Have you reviewed a          12 suspicious order report for McKesson?          13 A. Have I ordered -- reviewed a          14 suspicious order report? Which          15 particular report and particular time          16 period --          17 Q. Have you reviewed -- have          18 you reviewed any suspicious order report          19 from McKesson?          20 A. I have reviewed suspicious          21 order reports from McKesson. It's called          22 a variety of different names, but yes.          23 Q. How long does it take a          24 regulatory affairs employee to review a</p>	<p style="text-align: right;">Page 336</p> <p>1 look at Page 76 of your report.          2 A. Sure.          3 Q. And here we are in          4 Section 9.5.4 which is titled "As early          5 as 2005, McKesson knew its SOM program          6 was not in compliance with DEA          7 requirements."          8 Are you there, sir?          9 A. 76, 9.5.4, right?          10 Q. Yes, sir.          11 A. I'm here.          12 Q. Let's look at the last          13 paragraph on this page.          14 A. Absolutely.          15 Q. And it states, "At a later          16 meeting between McKesson and the DEA in          17 January of 2006, the DEA highlighted six          18 more McKesson pharmacy customers in          19 Florida which were purchasing large          20 quantities of hydrocodone."          21 Do you see that, sir?          22 A. Yes, I do see that, yes, of          23 course.          24 Q. And in that paragraph you</p>
<p style="text-align: right;">Page 335</p> <p>1 suspicious order report?          2 A. Again, just reviewing the          3 report is not enough. You need to go          4 behind the order and find out the          5 background, pull the file, look at what          6 you have on file, know your customer.          7 There's a significant amount of workload          8 there.          9 Q. Do you know how long it          10 takes a regulatory affairs employee to          11 review and analyze a suspicious order          12 report?          13 A. I have no data on time          14 studies that they've done to review the          15 report.          16 MR. EPPICH: Why don't --          17 why don't we take a quick break.          18 THE VIDEOGRAPHER: Going off          19 the record at 4:00 p.m.          20 (Short break.)          21 THE VIDEOGRAPHER: Back on          22 record at 4:17 p.m.          23 BY MR. EPPICH:          24 Q. Dr. Whitehall, if we could</p>	<p style="text-align: right;">Page 337</p> <p>1 discuss two of the pharmacies in the next          2 few sentences. First one is Bi-Wise          3 Pharmacy.          4 Do you see that?          5 A. I do see that.          6 Q. And the second is Avee          7 Pharmacy, A-V-E-E.          8 A. I do.          9 Q. Are you aware that McKesson          10 terminated sales with the Bi-Wise          11 Pharmacy and Avee Pharmacy?          12 A. No, I was not aware that          13 they actually terminated them.          14 Q. So you did not consider          15 those terminations in forming your          16 opinions expressed in your report, sir?          17 A. I did not consider those          18 terminations relevant to the point I was          19 making here, which was that DEA was          20 telling McKesson back in January of 2006          21 that it had customers that were          22 purchasing large amounts of hydrocodone          23 in this case and asking why. And why          24 were -- why were these sales not</p>

<p style="text-align: right;">Page 338</p> <p>1 considered suspicious. Yes, that was why  2 they were offered, but...</p> <p>3 Q. Sir, are you aware that  4 McKesson also terminated sales to the  5 other four pharmacies?</p> <p>6 MR. BOGLE: Objection to  7 form. Vague as to time.</p> <p>8 THE WITNESS: Again, to the  9 point, do we know if -- can you be  10 more specific as to when they  11 terminated them?</p> <p>12 BY MR. EPPICH:</p> <p>13 Q. Sir, I'm just asking you,  14 are you aware that McKesson terminated  15 sales to the other four pharmacies,  16 United Prescription Services, Universal  17 Rx, Medipharma Rx, and Accumed Pharmacy?</p> <p>18 A. Again, no, I was not. But  19 again, I was offering -- the look of the  20 discussion here was about the fact that  21 you were being put on -- McKesson was  22 being put on notice it had pharmacies  23 that were getting high amounts of opioids  24 in that particular period of time.</p>	<p style="text-align: right;">Page 340</p> <p>1 forming your opinions that are expressed  2 in your report?</p> <p>3 MR. BOGLE: Objection.  4 Asked and answered.</p> <p>5 THE WITNESS: Again, as I  6 was discussing, we were talking  7 about the sales to pharmacies,  8 those pharmacies in particular,  9 DEA telling McKesson that they  10 were purchasing large amounts of  11 opioids at that particular point  12 in time is putting McKesson on  13 notice that there were issues.</p> <p>14 Did I look at the  15 terminations after that fact? I  16 am not aware of having done so.</p> <p>17 BY MR. EPPICH:</p> <p>18 Q. Let's go ahead and turn to  19 Page 82 of your report. I want to  20 discuss the first sentence.</p> <p>21 A. Okay. I'm getting there,  22 please. Thank you.</p> <p>23 Q. Yes, sir.  24 And here -- here, sir, we</p>
<p style="text-align: right;">Page 339</p> <p>1 MR. EPPICH: Move to strike  2 everything after "again I was  3 not."</p> <p>4 BY MR. EPPICH:</p> <p>5 Q. Sir, did you consider those  6 terminations of those four pharmacies in  7 forming your opinions that are expressed  8 in your report?</p> <p>9 A. I considered those four  10 pharmacies in informing my report, based  11 on the fact they were getting high  12 amounts of opioids in that particular  13 period of time, and I was putting  14 McKesson on notice.</p> <p>15 But in the case of those  16 particular pharmacies' terminations, it  17 was not germane to the discussion.</p> <p>18 Q. My apologies, sir. Let me  19 restate my question because it was not  20 clear.</p> <p>21 Did you consider the  22 terminations of these four pharmacies,  23 United Prescription Services, Universal  24 Rx, Medipharma Rx, and Accumed Pharmacy in</p>	<p style="text-align: right;">Page 341</p> <p>1 are in Section 9.5.6, "Under the CSMP,  2 threshold setting combined with other  3 techniques resulted in a SOM program that  4 continued to be noncompliant with the  5 basic DEA requirements for controlled  6 substances, as well as the terms of the  7 company's 2008 settlement agreement."</p> <p>8 And here on Page 82, I want  9 to discuss the first sentence in the  10 third full paragraph, which states:  11 "Finally, the way the CSMP was  12 structured, McKesson was not looking for  13 suspicious orders, but instead for  14 suspicious customers."</p> <p>15 Do you see that, sir?</p> <p>16 A. Yes, I see that.</p> <p>17 Q. And there's a Footnote 381  18 after that sentence.</p> <p>19 Do you see that, sir?</p> <p>20 A. I do see that, I do see the  21 footnote.</p> <p>22 Q. Now, the citation at  23 Footnote 381 says, "The W. Ihlenfeld  24 March 20, 2014, letter to G. Hobart at</p>

Page 342

1 1."  
2 Do you see that, sir?  
3 A. I do see that sir.  
4 Q. Your source for this opinion  
5 is the March -- strike that.  
6 William Ihlenfeld is the  
7 former U.S. attorney for the Northern  
8 District of West Virginia, is he not?  
9 A. I would have to see the  
10 letter, because again, I've looked at  
11 lots of letters. So if you have  
12 something in particular that you'd like  
13 me to answer, could you please show me  
14 the document we're talking about?  
15 Q. You're aware that this  
16 letter was written by the DOJ, correct?  
17 A. I do know that it was  
18 written by the DOJ, yes.  
19 Q. And you're aware that this  
20 letter, written by the DOJ, contains  
21 allegations, correct?  
22 A. Again, before I can comment  
23 fully on it, I would need to see the  
24 letter to refresh my recollection,

Page 343

1 please.  
2 Q. Well, you're relying on this  
3 as a basis for this statement. And I  
4 think it's important for at least the  
5 court to know whether or not you're  
6 considering allegations and know you're  
7 considering allegations, or if you're  
8 considering a factually based document?  
9 MR. BOGLE: Object to form.  
10 BY MR. EPPICH:  
11 Q. Do you know, sir, are you  
12 relying on the allegations of the DOJ in  
13 forming the opinion of the statement that  
14 I just read?  
15 MR. BOGLE: Object to form.  
16 THE WITNESS: Again, as I  
17 said to you, in order to be able  
18 to answer your question, I need to  
19 see the documents. If you'd like  
20 to show me the document, I'm  
21 willing to have a conversation  
22 with you about it. But you're  
23 asking me to try to remember one  
24 of a lot of documents I looked at.

Page 344

1 And in a 300-page report, I'm just  
2 not willing to go down that path  
3 with you.  
4 BY MR. EPPICH:  
5 Q. Well, as a lawyer, sir, you  
6 understand that allegations in a letter  
7 are not evidence, correct?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: I'm not sure I  
10 understand your question.  
11 BY MR. EPPICH:  
12 Q. Are allegations evidence,  
13 sir?  
14 A. Allegations evidence?  
15 Again, I'm not sure what you're asking.  
16 It's a confusing question. What are you  
17 asking?  
18 Q. Are allegations of a  
19 complaint considered evidence, sir, or do  
20 they have to be proven in a court of law?  
21 A. Again, pardon me for being  
22 pedantic. I'm not sure what you're  
23 trying to ask me for for the standpoint  
24 of this report. Let me try to answer

Page 345

1 what I can for you from the standpoint of  
2 where I think you may be trying to ask.  
3 I think I'm hearing from you is that  
4 would I consider, you know, a written  
5 letter from DEA, if I was a compliance  
6 officer, as something, that I needed to  
7 take into account and adjust my  
8 compliance program for, if I were getting  
9 allegations or a letter from them, yeah,  
10 I would.  
11 I would certainly evaluate  
12 it and take it into account. It's not  
13 something that you discount lightly.  
14 Statements by regulators  
15 should never be discounted lightly. But  
16 I'm not sure what particular procedural  
17 point you're trying to make.  
18 Q. What actual evidence are you  
19 relying on in support of your opinion  
20 that, "The way the CSMP was structured,  
21 McKesson was not looking for suspicious  
22 orders, but instead for suspicious  
23 customers," as written on Page 82?  
24 A. Again, I cite to the

<p style="text-align: right;">Page 346</p> <p>1 document. I would need to see the                  2 document to refresh my recollection.                  3 Q. Let's look down the same                  4 page to the title Section B, "Threshold                  5 buffers."                  6 Do you see that?                  7 A. I do.                  8 Q. Now, the first sentence in                  9 this section states, "McKesson further                  10 weakened the value of using thresholds as                  11 a diversion prevention tool by factoring                  12 in buffers."                  13 Do you see that, sir?                  14 A. I do see it.                  15 Q. Now, if we go to Page 83,                  16 the second full paragraph, your report                  17 states, "This justification does not make                  18 sense. If McKesson needed a 25 percent                  19 buffer to account for purchasing pattern                  20 variation, that suggest that McKesson did                  21 not really know their customers as they                  22 were charged with doing by the DEA."                  23 Did I read that correctly?                  24 A. Yeah, you did.</p>	<p style="text-align: right;">Page 348</p> <p>1 testimony.                  2 THE WITNESS: You're                  3 misstating the report and you're                  4 misstating what I'm saying.                  5 Actually, the context of the                  6 report, if you go back -- let's go                  7 back up to the paragraph above                  8 that reads and starts with the                  9 sentence, "In September 2014,                  10 Nathan Hartle advised Michael                  11 Bishop, a regulatory affairs                  12 manager, to use a 25 percent                  13 buffer in writing. 'We have used                  14 the 25 percent in the past, so                  15 that's what I would put in place                  16 for now.' In his deposition,                  17 Mr. Hartle attempted to justify                  18 the use of the buffer by arguing                  19 'there's a significant variation                  20 in purchasing patterns at times.'"                  21 The point that I'm making                  22 here is that it had a universal                  23 25 percent buffer based on                  24 historical -- what you've done</p>
<p style="text-align: right;">Page 347</p> <p>1 Q. Now, we talked earlier                  2 about -- about quotas set by the DEA,                  3 correct?                  4 A. We did.                  5 Q. Are you aware that DEA                  6 applied a buffer to quotas that it set                  7 for opioids?                  8 A. I did not look in detail at                  9 the quota system. No, I was not aware.                  10 Q. Did you know that the DEA                  11 applied a 25 percent buffer to opioid                  12 quotas?                  13 A. Again, no, I was not. But                  14 it was not germane to this -- what I'm                  15 talking about here.                  16 Q. Would a -- if I understand                  17 your opinions correctly. A 25 percent                  18 buffer is not appropriate for McKesson to                  19 apply, but a 25 percent buffer is                  20 appropriate for the DEA to apply?                  21 MR. BOGLE: Object to form.                  22 BY MR. EPPICH:                  23 Q. Do I understand that, sir?                  24 MR. BOGLE: Misstates his</p>	<p style="text-align: right;">Page 349</p> <p>1 historically and not make                  2 adjustments for the fact that you                  3 have individual customers and                  4 individual patterns and you've                  5 had -- time has advanced, that                  6 rationale did not make sense to me                  7 as a compliance expert.                  8 BY MR. EPPICH:                  9 Q. Well, sir, knowing now that                  10 the DEA applied a 25 percent buffer to                  11 opioid quotas, does that change any of                  12 the opinions that you've reached --                  13 A. Absolutely not.                  14 Q. -- in Section B?                  15 If we can look at Page 87.                  16 Page 87 is, has a section entitled "E.                  17 Customer Due Diligence or Level 1                  18 Review."                  19 Do you see that?                  20 A. Yes, I see it.                  21 Q. And in this section you                  22 discuss the Tug Valley Pharmacy?                  23 A. I do indeed.                  24 Q. Now, Tug Valley Pharmacy is</p>



Page 350

1 not located in Summit County, correct?  
2 A. That is correct.  
3 Q. Tug Valley Pharmacy is not  
4 located in Cuyahoga County, correct?  
5 A. Yes, that's correct.  
6 Q. Do Pages 87 and 88 of your  
7 report contain all of the opinions that  
8 you plan to offer on Tug Valley Pharmacy,  
9 sir?  
10 A. At the moment, unless facts  
11 and circumstances change, yes.  
12 Q. If we can turn to Page 97,  
13 sir. 97 there's a Section 9.6.2 titled  
14 "McKesson's Implementation of the AGI  
15 Model."  
16 A. Yeah, I see it.  
17 Q. I want to look at the middle  
18 of the last paragraph on this page. It  
19 starts -- it's three lines down, sir. It  
20 says, "Based on my review of the AGI  
21 process, I believe that it suffers from  
22 at least one serious flaw. [REDACTED]  
[REDACTED]  
[REDACTED]

Page 351

1 during an ongoing epidemic. Therefore,  
2 it is difficult to see how setting  
3 thresholds using these methodologies will  
4 serve to reduce McKesson's opioid  
5 distribution to pre-epidemic levels."  
6 Do you see that, sir?  
7 A. Yes, I do see it.  
8 Q. In your opinion, what should  
9 the AGI model use instead of comparisons  
[REDACTED]  
11 A. I'm afraid I'm not  
12 understanding your question here.  
13 Q. Well, you opine here on Page  
14 97 that the AGI model suffers from one  
15 serious flaw.  
16 A. I did.  
17 Q. And you say, "The model  
18 threshold options both utilize  
19 comparisons [REDACTED]  
20 during an ongoing epidemic."  
21 Do you see that, sir?  
22 A. I do see that.  
23 Q. And my question for you is,  
24 what should the AGI model use instead of

Page 352

1 these comparisons [REDACTED]  
[REDACTED]  
3 A. I think you're missing the  
4 point that I was making, which is what  
5 happens, as the thresholds have continued  
6 to increase and gone up and up and up and  
7 up, and now you're using the thresholds  
8 at 1995 levels, no one, as far as I can  
9 see, I did not see any evidence that  
10 McKesson has gone back to look to see  
11 whether those threshold levels are at the  
12 right -- are the right levels or not, or  
13 just simply looking at, we've gotten to  
14 this number and that's what we're going  
15 to use, and we're going to continue to  
16 use this as the basis moving forward. I  
17 didn't see any hard examination of that  
18 fact.  
19 Q. Are you familiar with the  
20 AGI process, sir, the methodologies in  
21 McKesson's program?  
22 A. I am familiar with it from  
23 a -- my general reading on this case,  
24 yes. I am not a statistician nor do I

Page 353

1 offer statistic -- an opinion on a  
2 statistician. I offer it as a compliance  
3 expert and a process guy.  
4 Q. Are you aware that  
5 McKesson's AGI SOM program [REDACTED]  
[REDACTED]  
[REDACTED]  
8 A. Yes, I am aware of the  
9 algorithms.  
10 Q. And do you know how those  
11 algorithms work?  
12 A. Only in general terms.  
13 Again, I do not -- I'm not a  
14 biostatistician. I'm not a statistician.  
15 It's not my area.  
16 Q. Is it -- is it your  
17 understanding that the AGI model [REDACTED]  
[REDACTED]  
[REDACTED]  
20 A. The point I was making is  
21 the AGI model sets thresholds based on  
22 [REDACTED]  
[REDACTED] You're already  
24 at excessive levels or large levels,

<p style="text-align: right;">Page 354</p> <p>1 let's put it that way, and you're simply  2 building off of those already large  3 levels.  4 Q. Sir, what documents did you  5 review to learn about the McKesson AGI  6 SOM program?  7 A. I believe they are listed in  8 my report in the footnotes. Would you --  9 we can go through every one of the  10 footnotes if you'd like.  11 Q. Let's turn to Page 98 of  12 your report, sir.  13 A. Absolutely.  14 Q. Page 98 sets forth  15 Section 9.7, "Accountability - Consistent  16 Enforcement."  17 A. I do, I see it.  18 Q. And here you have a section  19 entitled 9 -- it's Section 9.7.1,  20 "Despite repeated breaches of company  21 policies and DEM" -- "DEA SOM  22 requirements, McKesson failed to  23 discipline those involved."  24 Do you see that, sir?</p>	<p style="text-align: right;">Page 356</p> <p>1 did you get this information?  2 A. I haven't seen anything that  3 says that that is factually incorrect.  4 Perhaps you'd like to share with me what  5 you have that is, and we can look at it  6 from there.  7 Q. Have you spoken to  8 Mr. Walker?  9 A. No, sir. I have not spoken  10 to Mr. Walker directly.  11 Q. Have you personally  12 interviewed Mr. Walker?  13 A. Sir, I reviewed his  14 deposition testimony, among other things.  15 Q. How long did you spend  16 reviewing the deposition testimony of  17 Mr. Walker?  18 A. I can't tell you how many  19 hours precisely I spent reviewing his  20 deposition testimony.  21 Q. Was it more than one hour?  22 A. Yes, it was more than one  23 hour.  24 Q. Was it more than five hours?</p>
<p style="text-align: right;">Page 355</p> <p>1 A. Yes, sir, I do.  2 Q. Now, let's look at the first  3 employee that you have identified under  4 A, Donald Walker.  5 Do you see that, sir?  6 A. I see -- I see Donald  7 Walker.  8 Q. Now, your report says, "As  9 the senior vice president for distributor  10 operations, Mr. Walker headed up the SOM  11 program from 1997 to 2015 having retained  12 his position after the first settlement."  13 Do you see that, sir?  14 A. I do.  15 Q. Now, I notice you did not  16 provide a source for your statement  17 there; is that correct?  18 A. I don't see a footnote  19 there, no.  20 Q. Well, the reason I'm curious  21 is because your sentence is factually  22 incorrect. Mr. Walker did not head  23 McKesson's SOM program from 1997 to 2015.  24 So my question for you is, where -- where</p>	<p style="text-align: right;">Page 357</p> <p>1 A. I have no idea from there.  2 Q. Did you review the entire  3 transcript or just parts of the  4 transcript?  5 A. I'd have to go back and look  6 at my notes to be sure. But I believe I  7 looked at the entire transcript. But I  8 don't remember.  9 Q. Did you review every  10 exhibit?  11 A. Again, I don't remember.  12 Q. Did you review any documents  13 about Mr. Walker not provided to you by  14 the plaintiffs' counsel?  15 A. Not that I recall. But  16 again they were provided to me by  17 plaintiffs' counsel in response to my  18 request.  19 Q. Let's look at the next  20 employee, Blaine Snider in Section B.  21 A. Yep.  22 Q. Have you ever spoken  23 personally to Mr. Snider?  24 A. No, sir.</p>

<p style="text-align: right;">Page 358</p> <p>1 Q. Did you personally interview 2 Mr. Snider? 3 A. No, sir. 4 Q. The materials considered in 5 your report states that you reviewed 6 Mr. Snider's deposition transcript; is 7 that true? 8 A. That is true. 9 Q. And how long did you spend 10 reviewing Mr. Snider's transcript? 11 A. Again, I can't give you a 12 precise timeline. I don't know. 13 Q. Do you know if it was more 14 than an hour? 15 A. I'm sure it was more than an 16 hour. 17 Q. Do you know if you reviewed 18 the entire transcript or just parts of 19 the transcript? 20 A. I don't remember at this 21 period of time. 22 Q. Do you remember any 23 documents from Mr. Snider's transcript 24 that you did review?</p>	<p style="text-align: right;">Page 360</p> <p>1 notes, documents, as you were learning, 2 tracking, developing the opinions in 3 your -- 4 A. I might have -- I might 5 have -- I might have made notes. 6 MR. BOGLE: Let him finish. 7 BY MR. EPPICH: 8 Q. Do you have copies of these 9 notes, sir? 10 A. Not with me today, no. 11 Q. But you do at your home or 12 your office? 13 A. Yeah, I'm sure. 14 Q. Are these -- are these notes 15 handwritten or are they on your computer? 16 A. I honestly don't know. I'm 17 going to guess there may be some 18 handwritten, and some computer. I have 19 no idea. 20 Q. Have you provided those 21 notes to your counsel for production in 22 this case? 23 A. I have provided everything 24 counsel has asked me to provide.</p>
<p style="text-align: right;">Page 359</p> <p>1 A. Again, as I -- we can go 2 back and -- if you'd like we can go look 3 through the reliance list. But I can't 4 recall them off the top of my head. 5 Q. Did you take any notes from 6 your review of the transcript of 7 Mr. Snider? 8 A. I don't recall. 9 Q. Do you -- did you -- you 10 mentioned some -- that you took some 11 notes on -- on your review of the 12 deposition transcript of Mr. Walker. 13 A. I'm not sure where you're 14 referring to. 15 Q. Well, do you recall that 16 testimony you just provided to me, that 17 you took notes on the transcript of 18 Dr. Walker? 19 Let me strike that question. 20 I'll ask a simpler question. 21 A. I'm not sure I'm -- 22 Q. Sir, in preparation of your 23 expert reports, your first report and 24 your supplemental report, did you create</p>	<p style="text-align: right;">Page 361</p> <p>1 Q. Let's go ahead and look at 2 the next employee in Section C, William 3 de Gutierrez-Mahoney. Have you ever 4 spoken personally to Mr. Mahoney? 5 A. No. 6 Q. Did you interview 7 Mr. Mahoney? 8 A. No. 9 Q. The materials considered in 10 your report states that you reviewed 11 Mr. Mahoney's deposition transcript. 12 A. That is correct. 13 Q. And how long did you spend 14 reviewing his transcript? 15 A. More than an hour. 16 Q. Did you review the entire 17 transcript? 18 A. Again, I don't recall. 19 Q. You don't recall if you just 20 reviewed portions? 21 A. I don't. 22 MR. BOGLE: Objection. 23 Asked and answered. 24 BY MR. EPPICH:</p>

Page 362

1 Q. Did you review every single  
2 exhibit to his deposition?  
3 A. I don't recall.  
4 Q. How many documents for  
5 Mr. Mahoney did you review?  
6 MR. BOGLE: Objection to  
7 form. Vague and ambiguous.  
8 THE WITNESS: What do you  
9 mean by documents?  
10 BY MR. EPPICH:  
11 Q. How many McKesson documents  
12 that Mr. Mahoney authored or was copied  
13 on if a communication, did you review?  
14 A. I'm afraid I can't answer  
15 that. I don't know. Again, I looked at  
16 a lot of documents. I can't give you a  
17 number. I wasn't keeping score on who  
18 wrote what and how many -- and how many  
19 did they write. So I'm sorry. I don't  
20 have that.  
21 Q. Dr. Whitelaw, you never  
22 personally interviewed any of these men?  
23 A. No, sir, I did not.  
24 Q. And you never reviewed

Page 363

1 documents about them that were not  
2 selected for you by plaintiffs' counsel?  
3 A. I reviewed documents that  
4 were selected for me from the documents  
5 that were produced based on my request  
6 for documentation.  
7 Q. You know, I want to know,  
8 sitting here today, in Section 9.7, what  
9 right do you have to pass judgment on  
10 these men and call for their careers?  
11 MR. BOGLE: Object to form.  
12 Misstates the document.  
13 THE WITNESS: Number one, I  
14 didn't pass judgment. Number two,  
15 I didn't call for their careers.  
16 What I did say is these were men  
17 who were in substantial authority  
18 for running the program, and I  
19 would have expected McKesson to  
20 have taken appropriate action for  
21 the fact that the program was  
22 deficient, and these were the  
23 folks who were involved in running  
24 it, and I would have expected

Page 364

1 something to have been done about  
2 it, and I don't see that.  
3 BY MR. EPPICH:  
4 Q. But, sir, you've testified  
5 that you have no DEA experience.  
6 MR. BOGLE: Object to form.  
7 He said he didn't work for DEA.  
8 THE WITNESS: This is not a  
9 DEA-relevant issue. This is a  
10 corporate compliance relevant  
11 issue. And even so, the question  
12 is, they were substantially in  
13 charge of these programs. And I  
14 have not seen McKesson take any  
15 appropriate action to remove the  
16 people who were supposed to be  
17 running the program correctly and  
18 overseeing it, and they're  
19 accountable. There's no  
20 accountability that I could see.  
21 BY MR. EPPICH:  
22 Q. Sir, you have no experience  
23 working in the compliance department at a  
24 pharmaceutical distributor, correct?

Page 365

1 A. I have not worked for a  
2 pharmaceutical distributor, but I'm not  
3 sure how that's particularly relevant to  
4 this particular -- is particularly  
5 germane to this issue. Holding people  
6 accountable who are supposed to be  
7 running your compliance programs is  
8 pretty germane issue and simple issue  
9 across all the boards.  
10 Q. Well, I think it's relevant,  
11 sir, because you took it upon yourself to  
12 name three of McKesson's employees in  
13 your report as employees that McKesson  
14 should have taken some form of  
15 disciplinary action against.  
16 And I would like to know  
17 what basis you have for making these  
18 allegations in your report, sir?  
19 MR. BOGLE: Object to form.  
20 THE WITNESS: My  
21 experience --  
22 MR. BOGLE: Go ahead.  
23 THE WITNESS: My experience  
24 sitting here as a compliance

Page 366	Page 368
<p>1 officer and having dealt with 2 people in similar situations who 3 have failed to do their job, puts 4 me in a position to say, based on 5 the record that I have reviewed, 6 there is enough here to say 7 somebody should have taken some 8 action here. 9 BY MR. EPPICH: 10 Q. That record, sir, are the 11 documents and testimony provided to you 12 by plaintiffs' counsel, correct? 13 MR. BOGLE: Objection. 14 Asked and answered. 15 THE WITNESS: Those 16 documents and record are what I 17 got in response to my request to 18 understand McKesson's program. 19 BY MR. EPPICH: 20 Q. By plaintiffs' counsel, 21 correct? 22 MR. BOGLE: Asked and 23 answered. 24 You can answer again.</p>	<p>1 notes, yeah. 2 MS. SWIFT: Can we have it 3 before the exam instead of after? 4 MR. BOGLE: Has he taken 5 notes today, yeah. 6 MS. SWIFT: Does he have 7 anything else for us? 8 If you have them with you, 9 are you going to give them to us? 10 MR. BOGLE: Yeah, sure. 11 When you get up to ask questions, 12 I'll give them to you. 13 You haven't made any 14 document requests. So when you 15 ask the question asking for a 16 document, you get documents. 17 You haven't made document 18 requests in your deposition 19 notice. So if you wanted 20 documents before the deposition, 21 you should have asked for them. 22 MS. SWIFT: I'm asking for 23 them right now. 24 MR. BOGLE: When you get up</p>
Page 367	Page 369
<p>1 THE WITNESS: By plaintiffs' 2 counsel. 3 MR. EPPICH: Thank you, sir. 4 I'll pass the witness. Let's go 5 off the record. 6 MR. BOGLE: Before we go 7 off, just to make clear, because I 8 don't want you guys having a beef 9 with this. He does have a couple 10 pages of specific McKesson notes 11 here. So if you want to look at 12 that. Because you asked him about 13 notes, and I think he forgot about 14 the fact that he's got two pages 15 here. 16 MR. EPPICH: No. That's 17 terrific. You know, let's go on a 18 break, and we'll just go ahead and 19 make a copy of everything in that 20 binder that's notes or note-like. 21 MS. SWIFT: Brandon, do you 22 know if he's got anything else for 23 us? 24 MR. BOGLE: Has he taken</p>	<p>1 and ask questions, we'll give them 2 to you. 3 MR. GOETZ: There's a 4 distinction between notes that he 5 made when he's reviewing his 6 report when he's preparing his 7 draft and notes that he made that 8 he might refer to today during 9 testimony. 10 MR. BOGLE: Right. 11 MR. GOETZ: There is not 12 ruling in this case that says that 13 you're entitled to notes that he 14 made when he's reviewing 15 deposition testimony. 16 MR. BOGLE: Right. What we 17 have here today are the notes he 18 has potentially got -- 19 MR. GOETZ: And he thought 20 he might look at those notes while 21 he was testifying. 22 MR. EPPICH: Let's go off 23 the record. 24 THE VIDEOGRAPHER: Going off</p>



<p style="text-align: right;">Page 370</p> <p>1 the record 4:44 p.m.  2 (Short break.)  3 THE VIDEOGRAPHER: We are  4 back on the record at 5:01 p.m.  5 - - -  6 EXAMINATION  7 - - -  8 BY MS. SWIFT:  9 Q. Good afternoon,  10 Mr. Whitelaw. My name is Kate Swift, and  11 I represent Walgreens in this case. When  12 we were off the record, I asked your  13 counsel for the notes that I understand  14 you have with you today that you prepared  15 while reviewing documents and depositions  16 in this case. And your counsel declined  17 to provide me those notes.  18 I will ask again, now that  19 we're back on the record, will you please  20 provide the notes that you have that you  21 prepared while reading documents and  22 depositions in this case?  23 MR. BOGLE: So to be clear,  24 as soon as he relies on them from</p>	<p style="text-align: right;">Page 372</p> <p>1 prepared -- strike that.  2 You testified earlier today  3 that you prepared notes while reviewing  4 the deposition of -- I believe it was a  5 Dr. Walker at McKesson. Do you remember  6 that testimony?  7 A. Yes, Kate, I do.  8 Q. Do you have those notes with  9 you today, sir?  10 A. No, Kate, I do not.  11 Q. Do you have any notes with  12 you today that you prepared while  13 reviewing documents or testimony in this  14 case?  15 MR. BOGLE: You can ask him  16 about Walgreens. He's done with  17 the general stuff. If you want to  18 rephrase as to Walgreens, go  19 ahead.  20 MS. SWIFT: Are you going to  21 instruct him not to answer that I  22 just asked?  23 MR. BOGLE: I am, yeah,  24 unless you're asking --</p>
<p style="text-align: right;">Page 371</p> <p>1 the deposition, I think you can  2 have them. At that point he's  3 relied upon them. Otherwise,  4 you're not entitled to draft --  5 anything he's created in the  6 drafting process.  7 Unless you guys are saying  8 across the board, then we need all  9 your experts' notes they created  10 in drafting their reports.  11 MR. GOETZ: And I want to be  12 clear. I did not indicate to you  13 that the notes that he had with  14 him today were those notes that he  15 made while he was reviewing  16 documents, while he was reviewing  17 testimony.  18 What I had indicated to you  19 were those notes he had made that  20 he thought he might rely upon or  21 refer back to in order to aid in  22 his testimony.  23 BY MS. SWIFT:  24 Q. Mr. Whitelaw, you</p>	<p style="text-align: right;">Page 373</p> <p>1 MS. SWIFT: What's the basis  2 of the instruction?  3 MR. BOGLE: The court's  4 order as to what subsequent  5 examiners are allowed to examine  6 on, which is their defendant. You  7 are Walgreens I believe, right?  8 MS. SWIFT: If you're going  9 to instruct the witness not to  10 answer general questions, we're  11 going to need to call Special  12 Master Cohen.  13 MR. BOGLE: Go ahead.  14 MS. SWIFT: Go off the  15 record.  16 THE VIDEOGRAPHER: Off the  17 record. 5:03 p.m.  18 (Brief recess.)  19 THE VIDEOGRAPHER: Back on  20 the record at 5:06 p.m.  21 BY MS. SWIFT:  22 Q. Mr. Whitelaw, did you  23 prepare notes while you were reviewing  24 documents and depositions in the course</p>

<p style="text-align: right;">Page 374</p> <p>1 of your work on this case?</p> <p>2 A. Yes, I did.</p> <p>3 Q. What did you do with those</p> <p>4 notes?</p> <p>5 A. Kept one. I'm not sure --</p> <p>6 can you be more precise when you say what</p> <p>7 did I do with those notes.</p> <p>8 Q. I mean, did you put them in</p> <p>9 a drawer somewhere, did you use them for</p> <p>10 any purpose after you prepared the notes?</p> <p>11 A. Again, I can't tell you</p> <p>12 whether I used them for any purpose after</p> <p>13 I prepared the notes. I maintained the</p> <p>14 notes. I've held onto them. I'm not</p> <p>15 sure what you're looking for.</p> <p>16 Q. The notes didn't form the</p> <p>17 first draft of your report?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 Vague and ambiguous.</p> <p>20 THE WITNESS: Can you be</p> <p>21 more precise?</p> <p>22 BY MS. SWIFT:</p> <p>23 Q. Do you know what a draft of</p> <p>24 a report is?</p>	<p style="text-align: right;">Page 376</p> <p>1 you mean by formed. So did I -- did I</p> <p>2 use them to refer back to documents when</p> <p>3 I was working on drafting the report,</p> <p>4 yes.</p> <p>5 But formed, I don't know</p> <p>6 what you mean by formed.</p> <p>7 Q. All right. Then we'll</p> <p>8 request again production of all the notes</p> <p>9 that you prepared while reading documents</p> <p>10 and testimony in -- in your work on this</p> <p>11 case.</p> <p>12 MR. BOGLE: Are you guys</p> <p>13 doing the same thing for all your</p> <p>14 experts? It appears to be</p> <p>15 contrary to CMO 1. So if you guys</p> <p>16 want to go back on all that, then</p> <p>17 I think that's a much broader</p> <p>18 discussion than just for this</p> <p>19 deposition.</p> <p>20 MS. SWIFT: I don't hear him</p> <p>21 telling me that he used it to form</p> <p>22 a draft of his report.</p> <p>23 MR. BOGLE: I don't -- I</p> <p>24 don't hear him saying anything</p>
<p style="text-align: right;">Page 375</p> <p>1 A. Yes, I know what a draft of</p> <p>2 a report is.</p> <p>3 Q. Did the notes that you</p> <p>4 prepared when you were reviewing</p> <p>5 documents and testimony form the first</p> <p>6 draft of your report?</p> <p>7 MR. BOGLE: Object to form.</p> <p>8 Vague and ambiguous.</p> <p>9 THE WITNESS: Again, I know</p> <p>10 what a draft is, Kate. I don't</p> <p>11 know what you're asking me.</p> <p>12 Are you asking me did I</p> <p>13 write -- handwrite my first draft</p> <p>14 in my report? I'm not sure I'm</p> <p>15 understanding you.</p> <p>16 BY MS. SWIFT:</p> <p>17 Q. I didn't ask you if you</p> <p>18 handwrote your draft of your report.</p> <p>19 I asked you if the notes</p> <p>20 that you took while you were reading</p> <p>21 documents and depositions in this case</p> <p>22 formed the first draft or any draft of</p> <p>23 your report.</p> <p>24 A. And again, I don't know what</p>	<p style="text-align: right;">Page 377</p> <p>1 that makes these discoverable. So</p> <p>2 that's fine. You can request</p> <p>3 whatever you want. You ain't</p> <p>4 getting them, but you can request</p> <p>5 them.</p> <p>6 BY MS. SWIFT:</p> <p>7 Q. Mr. Whitelaw, you understand</p> <p>8 that the court's rules require you to</p> <p>9 disclose all of your opinions in your</p> <p>10 report, correct?</p> <p>11 A. Yes.</p> <p>12 Q. You also understand that the</p> <p>13 rules require you to include the bases or</p> <p>14 reasons supporting those opinions in your</p> <p>15 report?</p> <p>16 A. Yes.</p> <p>17 Q. Are all of your opinions</p> <p>18 included in your report?</p> <p>19 A. And supplemental report,</p> <p>20 yes, to the best of my knowledge.</p> <p>21 Q. Are -- are all of the bases</p> <p>22 for your opinions included in your</p> <p>23 original report and your supplemental</p> <p>24 report?</p>

Page 378

1 A. Again, Kate, to the best of  
2 my knowledge, yes.  
3 Q. And -- and you understand  
4 the point of those rules is so that we  
5 can look at your report in advance of the  
6 deposition and then ask you questions  
7 about the opinions and the bases or what  
8 supports those opinions. You understand  
9 that, right?  
10 A. I understand it. I also  
11 understand that just basic good  
12 scholarship is you have to support your  
13 opinions. So yes, I understand the  
14 concepts.  
15 Q. If it's not in your report,  
16 we can't do that, you understand that,  
17 sir, right?  
18 MR. BOGLE: Object to form.  
19 THE WITNESS: Yes, I  
20 understand it. Yes, I understand  
21 that.  
22 BY MS. SWIFT:  
23 Q. Throughout your report you  
24 include footnotes with citations to

Page 379

1 documents and testimony. Is it fair to  
2 say that those documents and that  
3 testimony provide the specific support  
4 for whatever you've just said in the body  
5 of the report that's leading up to the  
6 footnote?  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: Can you  
9 rephrase the question, because  
10 again it's -- can you re-ask me  
11 the question, because I lost the  
12 train of thought.  
13 BY MS. SWIFT:  
14 Q. You have footnotes in your  
15 report, correct, sir?  
16 A. Yes, I do.  
17 Q. Is it fair to say that the  
18 citations that appear in the footnotes of  
19 your report provide the specific support  
20 for whatever it is you have just said in  
21 the body of the report leading up to the  
22 footnote?  
23 A. That's usually how you use  
24 footnotes, but, yes.

Page 380

1 MR. BOGLE: Object to form.  
2 BY MS. SWIFT:  
3 Q. So if we wanted to figure  
4 out what your basis was for a specific  
5 point you've made in the body of the  
6 report, we could look at the footnotes;  
7 is that fair?  
8 A. That's where I would start  
9 myself, yes.  
10 Q. Well, you said that's where  
11 you would start. Is there -- are you  
12 trying to say that there's some  
13 support --  
14 A. No, I'm --  
15 MR. BOGLE: Hold on. Let  
16 her finish.  
17 THE WITNESS: I'm sorry.  
18 BY MS. SWIFT:  
19 Q. My question is -- well,  
20 strike that.  
21 Your report is hundreds of  
22 pages long; is that fair, sir?  
23 A. Yes, it is.  
24 Q. And you also have attached a

Page 381

1 lengthy list of reliance materials,  
2 correct, sir?  
3 A. That is correct.  
4 Q. So if we want to figure out  
5 what the specific support is for a  
6 particular point in the body of the  
7 report, is it fair to say we could start  
8 and end with the footnote --  
9 A. Yes.  
10 Q. -- that's cited?  
11 MR. BOGLE: Wait until she  
12 finishes the question.  
13 BY MS. SWIFT:  
14 Q. You're not going to come to  
15 trial and offer different support than  
16 what you've provided in the footnotes of  
17 the report, are you, sir?  
18 MR. BOGLE: Object to form.  
19 THE WITNESS: Well, I'm not  
20 sure I completely understand your  
21 question. If there are facts and  
22 circumstances that change, new  
23 evidence that comes about, I have  
24 reserved the right to amend the

<p style="text-align: right;">Page 382</p> <p>1 report as you know.                  2 But I'm not sure, so I'm not                  3 sure what your question is.                  4 BY MS. SWIFT:                  5 Q. Well, let me put it this                  6 way. If you have any additional things                  7 you want to tell us about or that you --                  8 at trial, you're saying you're going to                  9 supplement your report and potentially                  10 provide additional footnotes and that's                  11 how we'll know what those supplemental                  12 opinions are; is that fair?                  13 A. Again, if there's stuff that                  14 needs to be addressed prior to testimony                  15 and yeah, it needs to be -- and this body                  16 of work needs to be updated, I would                  17 provide a supplemental report.                  18 Q. I believe you told my                  19 colleague earlier today that sitting here                  20 today, you don't have any intention to                  21 provide a supplemental report; is that                  22 right?                  23 A. As of this moment in time,                  24 no, I do not.</p>	<p style="text-align: right;">Page 384</p> <p>1 for compliance, no matter what kind of                  2 compliance, those best practices, that                  3 guidance can change over the years; is                  4 that fair?                  5 MR. BOGLE: Object to form.                  6 Vague and ambiguous.                  7 THE WITNESS: I think it's                  8 fair to say that compliance                  9 programs were never intended to be                  10 static, as I note in my report,                  11 that things change, compliance                  12 evolves, just like any other                  13 program.                  14 BY MS. SWIFT:                  15 Q. Would you agree that good                  16 companies evolve to improve their                  17 practices over time as guidance changes?                  18 A. I would say good -- I would                  19 say good companies take into account                  20 change in guidance, changing practice,                  21 changing business models and adapt.                  22 Q. You would agree that even a                  23 good company may never reach a perfect                  24 state of compliance?</p>
<p style="text-align: right;">Page 383</p> <p>1 Q. Would you agree with me,                  2 Mr. Whitelaw, that guidance on best                  3 practices for compliance changes over                  4 time?                  5 MR. BOGLE: Object to form.                  6 Vague and ambiguous.                  7 THE WITNESS: Can you be                  8 more specific? Are we talking                  9 about a specific area? Are we                  10 talking general? I'm not sure,                  11 when we say compliance, we need to                  12 be a bit more specific.                  13 BY MS. SWIFT:                  14 Q. Well, as I understand your                  15 testimony today, you hold yourself out as                  16 a compliance professional who has offered                  17 a variety of types of compliance services                  18 throughout your 30-some-odd-year career.                  19 Is that fair?                  20 A. That's a fair                  21 characterization.                  22 Q. So I just want to ask you in                  23 general terms, whether when you're                  24 talking about guidance on best practices</p>	<p style="text-align: right;">Page 385</p> <p>1 A. I'm going to need you to be                  2 more precise when you say "perfect state                  3 of compliance." What do you mean by                  4 perfect?                  5 Q. Well, you're a compliance                  6 professional. Do you have a definition                  7 that you use yourself for perfect                  8 compliance?                  9 A. Kate, it's not a term I use.                  10 I use the term "reasonable compliance."                  11 Q. Is that because a company --                  12 it would be unreasonable to expect a                  13 company to achieve perfect compliance?                  14 MR. BOGLE: Object to form.                  15 THE WITNESS: Again, we need                  16 to be clear what we're defining as                  17 perfect compliance. I'm not sure                  18 I understand what you mean by that                  19 term.                  20 BY MS. SWIFT:                  21 Q. Well, I asked you for your                  22 definition so we can talk on the same                  23 terms.                  24 A. Okay. If you're saying do I</p>

Page 386

1 believe that a customer will never make a  
 2 mistake, never fail to sign a piece of  
 3 paper or file a piece of paper on time or  
 4 things like that, do I believe that those  
 5 things will still happen even with the  
 6 compliance program? Yes, I think that's  
 7 fair to say.  
 8 Q. Is it fair to say that in  
 9 your view, even a good company will never  
 10 reach a perfect state of compliance?  
 11 MR. BOGLE: Object to form.  
 12 BY MS. SWIFT:  
 13 Q. Using your definition of the  
 14 term?  
 15 A. I think it's fair to say  
 16 that you will always have a -- there's  
 17 always a chance of making a misstep, yes,  
 18 even with -- even with the most robust of  
 19 compliance programs. It's not an  
 20 absolute guarantee, if that's what you're  
 21 asking me.  
 22 Q. The fact that a company  
 23 makes improvements over time to its  
 24 compliance program, that doesn't mean the

Page 387

1 company was necessarily in violation of  
 2 the law before the improvements were put  
 3 in place, right?  
 4 MR. BOGLE: Object to form.  
 5 Vague and ambiguous.  
 6 THE WITNESS: Again, I'm not  
 7 quite following you. When we're  
 8 talking about -- again, what law  
 9 are we talking about? What time  
 10 frame are we talking about? What  
 11 are you talking about in  
 12 particular?  
 13 BY MS. SWIFT:  
 14 Q. I wasn't talking about any  
 15 law in particular or any time frame.  
 16 A. I'm just trying -- I'm  
 17 trying to understand your question.  
 18 Q. We've talked a little bit  
 19 about the fact that it's a good thing for  
 20 companies to try to improve their  
 21 compliance programs over time, fair?  
 22 A. Fair.  
 23 Q. The fact that a company does  
 24 that, that it improves its compliance

Page 388

1 program over time, that doesn't mean that  
 2 the old program was in violation of the  
 3 law necessarily, does it?  
 4 MR. BOGLE: Object to form.  
 5 THE WITNESS: Again, without  
 6 any -- looking at facts and  
 7 circumstances, I can't tell you  
 8 whether it is or it isn't.  
 9 BY MS. SWIFT:  
 10 Q. Well, I mean you don't want  
 11 a company to not improve its program --  
 12 A. No, a company should  
 13 always --  
 14 MR. BOGLE: Wait for her to  
 15 finish.  
 16 BY MS. SWIFT:  
 17 Q. You don't want a company to  
 18 not improve its programs based on a  
 19 concern that if it does that, its past  
 20 programs would be considered  
 21 noncompliant, correct?  
 22 A. I think the problem with  
 23 your hypothetical is the fact that you  
 24 can't erase -- you can't erase the past.

Page 389

1 So the incentive is to always continually  
 2 improve and move forward. But what's  
 3 happened in the past has happened in the  
 4 past. So, again, I'm not sure the  
 5 relevance of the question.  
 6 Q. Well, I think you're  
 7 agreeing with me though. Let me see if I  
 8 understand what you're saying. I think  
 9 you have agreed that you wouldn't want a  
 10 company to -- I think static was the word  
 11 that you used. You wouldn't want a  
 12 company to be static in its compliance  
 13 programs, correct?  
 14 A. No, I would not expect to  
 15 see a good company be static in its  
 16 compliance.  
 17 Q. And you wouldn't want a good  
 18 company to be afraid to change its  
 19 compliance program out of a concern that  
 20 its past programs would be deemed  
 21 noncompliant, fair?  
 22 MR. BOGLE: Object to form.  
 23 THE WITNESS: Again, as I  
 24 said to you, since you can't erase



<p style="text-align: right;">Page 390</p> <p>1 the past, I don't understand the 2 nature of the question. It just 3 does not compute. I'm sorry. 4 BY MS. SWIFT: 5 Q. I'm -- it does not compute? 6 A. In my head it doesn't 7 compute. You can't -- you can't erase 8 the past, Kate. So whatever happened in 9 the past, has happened in the past. 10 So -- 11 Q. You've worked with companies 12 on compliance programs a lot over the 13 years; is that fair? 14 A. I have. 15 Q. When you're sitting with 16 your clients -- and I'm not asking about 17 any particular client. 18 A. I understand. 19 Q. Have you had occasion to 20 talk about improving that company's 21 compliance program? 22 A. Yes. 23 Q. And you wouldn't recommend 24 to a company not to improve their</p>	<p style="text-align: right;">Page 392</p> <p>1 Q. Mr. Whitelaw, I believe you 2 testified earlier today that you haven't 3 ever spoken to Dr. McCann, the 4 plaintiffs' expert? 5 A. That is what I did say to 6 you. 7 Q. And if you -- do you have 8 your report in front of you? 9 A. I do. 10 Q. And, actually, I think you 11 have a copy of it that's marked as 12 Exhibit 2. But you also have a binder 13 that you've been referring to throughout 14 the day; is that right? 15 A. It's my report, yes. 16 Q. Can we mark the binder as an 17 exhibit, please. And we can make a copy 18 of it or do whatever we need to do. 19 MR. BOGLE: Do you want to 20 put a sticker on it or do you want 21 me to? 22 MS. SWIFT: I'll put a 23 sticker on it. Let's mark it as 24 Exhibit 10.</p>
<p style="text-align: right;">Page 391</p> <p>1 compliance program out of a concern that 2 the past program would be deemed 3 noncompliant, would you? 4 A. Kate, I think it's -- in my 5 experience, what you're asking is a 6 completely hypothetical question, because 7 I never had that conversation. My 8 conversation with my clients have been, 9 we want to improve. No one has asked -- 10 has phrased that concern or asked it from 11 that particular point of view. 12 Q. Would you -- 13 A. That's why I don't 14 understand the question that you're 15 asking. 16 Q. Would you agree with me that 17 a fact that a company changes its 18 compliance program, improves its 19 compliance program, is a good thing? 20 A. In general, yes. 21 Q. That's what you want a 22 company to do, right? 23 A. You want a company to 24 improve, yes.</p>	<p style="text-align: right;">Page 393</p> <p>1 (Document marked for 2 identification as Exhibit 3 Whitelaw-10.) 4 BY MS. SWIFT: 5 Q. What is in the binder, 6 Mr. Whitelaw? 7 A. What's in the binder is a 8 copy of my report from April 15th. A 9 copy of my supplemental report. An extra 10 copy of the table of contents. And those 11 were the -- 12 Q. These are the notes that we 13 can't have? 14 A. Those are -- 15 MR. BOGLE: That's the 16 McKesson notes. 17 THE WITNESS: The McKesson 18 notes. 19 MR. BOGLE: I believe you 20 may have looked at it. So I'm 21 letting them have them. 22 MS. SWIFT: These notes we 23 can have? 24 MR. BOGLE: The McKesson</p>

<p style="text-align: right;">Page 394</p> <p>1 notes which I believe he may have 2 referred to, yes. 3 (Document marked for 4 identification as Exhibit 5 Whitelaw-11.) 6 MS. SWIFT: I'm going to 7 mark the McKesson notes as 8 Exhibit 11. 9 And then -- so I'm going to 10 set the McKesson notes aside. 11 BY MS. SWIFT: 12 Q. Then I think you said 13 there's an extra copy of the table of 14 contents -- 15 A. Just to make it easier 16 because it's -- again, it's a 300-page 17 report. 18 MR. BOGLE: Wait for her to 19 finish. 20 BY MS. SWIFT: 21 Q. And then the supplemental 22 report is also in here? 23 A. Yes, ma'am. 24 Q. And then everything that's</p>	<p style="text-align: right;">Page 396</p> <p>1 I'm not mistaken. 2 A. Okay. 3 Q. You have included under the 4 list of "Other Non-Publicly Available 5 Materials," a handful of citations to 6 Appendix 9 of Dr. McCann's report, 7 correct? 8 A. Yes, I did. 9 Q. Are the citations to 10 Appendix 9 that are listed here, the only 11 pages of Appendix 9 that you reviewed? 12 A. To the best of my 13 recollection, yes. 14 Q. Are the pages of Appendix 9 15 that you've cited here in your report the 16 only pages of -- of Dr. McCann's entire 17 report that you have reviewed? 18 A. Again, to the best of my 19 knowledge, yes. 20 Q. You did not review 21 Appendix 10 to Dr. McCann's report? 22 A. If it's not listed in my 23 reliance materials, then I don't recall 24 seeing it.</p>
<p style="text-align: right;">Page 395</p> <p>1 in the three-hole binder is the same as 2 the initial report that you served on 3 April 15th; is that correct? 4 A. Yes, I believe so. 5 Q. And it looks like you have 6 added some tabs, some of which have notes 7 on them. Is that fair? 8 A. That's fair. 9 Q. What was the purpose of the 10 tabs? 11 A. The purpose of the tabs are 12 to help me navigate when you ask me 13 questions, and trying to make things move 14 more efficiently. 15 Q. And you've also got your 16 appendices in here, right? 17 A. Mm-hmm. 18 Q. Great. All right. I'll 19 hand this back to you. There's that. 20 A. Thank you. 21 Q. All right. Turn -- turn if 22 you would please in Exhibit 10, the copy 23 of your report, to Page 278 which is in 24 your appendices. It's in Appendix I if</p>	<p style="text-align: right;">Page 397</p> <p>1 Q. And I just want to make a 2 clear yes or no on that because I know 3 we're focusing on one page of the 4 reliance materials, and I know there's a 5 lot of them in there. 6 Am I correct you did not 7 review Appendix 10 of Dr. McCann's 8 report? 9 Just yes or no. 10 MR. BOGLE: If you can 11 answer it yes or no. 12 THE WITNESS: I can't answer 13 it yes or no because I have no 14 idea what Appendix 10 might have 15 been. So I have no clue how to 16 answer this. 17 Other than -- other than to 18 say what you see in front of you 19 in my reliance materials is as 20 full and complete a list of 21 everything I looked at as I could 22 make. 23 BY MS. SWIFT: 24 Q. If you had reviewed</p>

Page 398

1 Appendix 10 of Dr. McCann's report, would  
2 that appear here on Page 278?  
3 A. I would -- it should have.  
4 Q. If you had reviewed  
5 Appendix 11 of Dr. McCann's report, would  
6 that have appeared in the same section of  
7 your reliance materials on Page 278?  
8 A. I believe so.  
9 Q. You don't recall sitting  
10 here today reviewing Appendix 10 or 11 of  
11 Dr. McCann's report?  
12 A. I do not recall reviewing  
13 Appendix 10 and 11 of Dr. McCann's  
14 report.  
15 Q. You never spoke with  
16 Dr. McCann?  
17 A. No, I never spoke with  
18 Dr. McCann.  
19 Q. Did you do anything to  
20 verify the charts or bar graphs that  
21 appear at these pages of Appendix 9 of  
22 Dr. McCann's report that you cite?  
23 A. You mean did I crank the  
24 numbers myself? I'm -- I'm not sure --

Page 399

1 Q. That's exactly what I mean.  
2 A. No, I did not.  
3 Q. Did you do anything to  
4 verify that Dr. McCann's charts  
5 accurately reflect the pharmacies where  
6 opioids got shipped?  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: Can you be  
9 more precise?  
10 BY MS. SWIFT:  
11 Q. What don't you understand  
12 about my question?  
13 A. I'm just trying to  
14 understand specifically what you're  
15 looking for. And you're asking a very  
16 broad question, do I understand  
17 pharmacies and opioid. I'm just trying  
18 to be precise in exactly what you want to  
19 know.  
20 Q. I asked you whether you did  
21 anything to verify that in the charts  
22 that Dr. McCann put together and that you  
23 cite in your expert report in this case,  
24 did you do anything to verify that those

Page 400

1 charts accurately reflected the  
2 pharmacies where the opioids in those --  
3 those charts got shipped?  
4 MR. BOGLE: Object to form.  
5 THE WITNESS: Again, I did  
6 not independently review the data  
7 or validate the data in  
8 Dr. McCann's report.  
9 BY MS. SWIFT:  
10 Q. I apologize if you answered  
11 this question earlier today and I just  
12 missed it. Did you read Mr. Rafalski's  
13 report?  
14 A. No, ma'am, I did not.  
15 Q. Turn if you would to Page 45  
16 of your report marked as Exhibit 10.  
17 Page 45 starts at Section 8.2, "Group 2  
18 Distributors," correct?  
19 A. Yes.  
20 Q. In the first paragraph of  
21 that section you say that you understand  
22 that the large national pharmacy or  
23 retail chains have distribution  
24 operations that only ever supplied

Page 401

1 opioids to their own pharmacies, correct?  
2 A. That was -- yes, that's what  
3 it says.  
4 Q. You understand that  
5 Walgreens only ever distributed opioid  
6 pain medication to its own pharmacies,  
7 correct, sir?  
8 MR. BOGLE: Objection.  
9 Asked and answered.  
10 THE WITNESS: From its own  
11 distribution centers? Yes, it  
12 only distributed to its own  
13 pharmacies, that's what I  
14 understand.  
15 BY MS. SWIFT:  
16 Q. Now, I'd like you to take a  
17 look at the fifth paragraph in that  
18 section, which is on Page 46. It's the  
19 paragraph that starts "again."  
20 Do you see that?  
21 A. Yes.  
22 Q. In the middle of that  
23 paragraph, you note that it's your  
24 understanding that in the 2008, 2009 time

<p style="text-align: right;">Page 402</p> <p>1 frame, the chain pharmacies took 2 meaningful efforts to meet their legal, 3 regulatory, and societal obligations, 4 correct?</p> <p>5 MR. BOGLE: Object to form. 6 THE WITNESS: I state that 7 the two Group 2 pharmacies that I 8 reviewed, Walgreens and CVS, and 9 that's an accurate statement. 10 BY MS. SWIFT: 11 Q. In the next paragraph, you 12 assert that none of these so-called G2 13 distributors -- well, strike the 14 question. The G2 distributors, does that 15 only include Walgreens and CVS? 16 A. Yes. 17 Q. Okay. In the next 18 paragraph, you assert that neither of the 19 G2 distributors tried to incorporate 20 their own dispensing data into their 21 anti-diversion programs. 22 Do you see that? 23 A. I see that. 24 Q. What's your basis for that</p>	<p style="text-align: right;">Page 404</p> <p>1 MR. BOGLE: Object to form. 2 THE WITNESS: Again, I'd 3 have to go through the complete 4 Walgreens section soup to nuts. 5 But to the best of my 6 recollection, I did not see 7 anything that showed, on a 8 systemic basis, that they were 9 using dispensing data as part of 10 the program. 11 BY MS. SWIFT: 12 Q. In the next paragraph on 13 Page 46, this is the paragraph that 14 starts "in addition." 15 Do you see that? 16 A. Yes. 17 Q. You state, "Those who were 18 charged with controlled substances 19 compliance invested substantial time and 20 resources trying not to classify 21 excessive pharmacy orders as suspicious, 22 so as not to disrupt product supply." 23 What is your basis for that 24 statement?</p>
<p style="text-align: right;">Page 403</p> <p>1 statement? 2 A. Having reviewed the 3 documents, having asked for the 4 information, having looked at what they 5 were using to determine suspicious order 6 monitoring, based on my review I did not 7 see them using dispensing data in their 8 own -- to try to clear red flags for 9 various suspicious orders. 10 Q. Am I correct that the 11 documents that you reviewed were provided 12 to you by the plaintiffs' counsel? 13 A. In request to my asking for 14 documents -- again, using the federal 15 sentencing guideline framework, I asked 16 for, show me documents around standard 17 operating procedures, training, 18 education. I asked for a lot of 19 documents. And, yes, they were provided 20 by counsel. 21 Q. You didn't see any documents 22 at all, none whatsoever, where Walgreens 23 employees were using dispensing data in 24 their suspicious order monitoring?</p>	<p style="text-align: right;">Page 405</p> <p>1 A. Well, would you like to turn 2 to the Walgreens section and we can walk 3 through it? Because it's based on my 4 document review, the depositions 5 reviewed, et cetera. But if we want to 6 get down to specifics, I can walk you 7 through it. 8 Q. Right now I'd just like to 9 ask you about the statement that I asked 10 you about on Page 46. And I don't see a 11 footnote for that statement here. Would 12 you agree with that, that there's no 13 footnotes cited on Page 46 for that 14 statement? 15 A. I would agree with you 16 there's no footnotes cited for that 17 statement on Page 46, yes. 18 Q. From your previous answer, I 19 take it that whatever basis you have for 20 the statement that Walgreens employees 21 invested substantial time and resources 22 trying not to classify excessive pharmacy 23 orders as suspicious so as not to disrupt 24 product supply, your support for that</p>

<p style="text-align: right;">Page 406</p> <p>1 statement is going to be in the section 2 of your report about Walgreens? 3 A. That's what I'm telling you. 4 Q. Have you ever talked to 5 anyone at Walgreens who told you they 6 were trying to avoid classifying pharmacy 7 orders as suspicious so as not to disrupt 8 product supply? 9 A. No, ma'am, I have not talked 10 to anybody at Walgreens. 11 Q. Is it your testimony that 12 you read that in a document somewhere? 13 A. It is my testimony that I 14 read it in documents somewhere. 15 Q. And I want to be clear with 16 my question. There was a pronounce in 17 there that might have been ambiguous. 18 Is it your testimony that 19 you read in a document somebody at 20 Walgreens saying in a document, we are 21 trying to avoid classifying pharmacy 22 orders as suspicious so as not to disrupt 23 product supply? Is that your testimony? 24 A. Are you asking me did I see</p>	<p style="text-align: right;">Page 408</p> <p>1 Q. I'm broadening it just a 2 little bit. Now I'm asking, okay, not 3 that verbatim language, but language that 4 has the same substance to it. Did you 5 see anything like that in the Walgreens 6 document? 7 MR. BOGLE: Object to form. 8 THE WITNESS: Yes, I did. 9 BY MS. SWIFT: 10 Q. What did you see? What 11 document? 12 A. It was a series of 13 documents. But document -- we can start 14 with Natasha Polster's deposition. 15 Q. Okay. What did she say? 16 What are you referring to? 17 A. Let's walk -- let's walk 18 through the report. 19 Q. The Walgreens section of the 20 report starts on Page 183. 21 A. That is correct. 22 Q. I'd like you to direct me to 23 what -- 24 A. I understand.</p>
<p style="text-align: right;">Page 407</p> <p>1 that exact direct quote? Is that what 2 you're looking for? I'm not -- 3 Q. Yes. That's what I'm asking 4 you. 5 A. No, I did not see that exact 6 direct quote. 7 Q. Did you see a document that 8 had the substance that I just included in 9 my previous question, maybe not the exact 10 quote, but somebody essentially saying, 11 hey, guys, let's invest time and 12 resources trying not to classify 13 excessive pharmacy orders as suspicious 14 so we won't disrupt our product supply? 15 MR. BOGLE: Object to form. 16 THE WITNESS: Could you be 17 more -- again, are you -- I'm not 18 sure exactly what you are looking 19 for me -- looking for to comment. 20 BY MS. SWIFT: 21 Q. Well, you said that you 22 didn't see a document with that exact 23 quotation in it. 24 A. No, I did not.</p>	<p style="text-align: right;">Page 409</p> <p>1 Q. -- testimony of Ms. Polster 2 that you were just referring to? 3 A. Mm-hmm, absolutely. Yeah, I 4 would say it starts at on Page 188, at 5 13.4.1, and continues onto 189. 6 Q. Is the specific testimony 7 that you're referring to from Ms. Polster 8 the testimony that "you have to take care 9 of the patient"? 10 A. No. Actually, that was part 11 of it. But if you want the rest of it, 12 it's the one on Page 189 that talks about 13 the Walgreens system. "The Walgreens 14 system was put into place to ensure 15 stores had proper quantities, not 16 necessarily to detect a red flag." 17 Q. Just to make sure that I'm 18 clear, the paragraph that we were looking 19 at before on Page 46, the paragraph that 20 said, "Those who were charged with 21 controlled substances compliance invested 22 substantial time and resources trying not 23 to classify excessive pharmacy orders as 24 suspicious so as not to disrupt product</p>



Page 410	Page 412
<p>1 supply," you testified the basis for that 2 statement with respect to Walgreens is 3 Ms. Polster's testimony that "you have to 4 take care of the patient" and -- 5 A. That's some of it. 6 Q. I'm not done. 7 -- and her further testimony 8 in answer to the question, "Now, 9 Walgreens system, similar to my alarm, is 10 there to detect a potential red flag. 11 Would you agree with that? 12 "Answer: It was put in 13 place to ensure that the stores had the 14 proper quantities, not necessarily to... 15 detect a red flag. The whole idea was to 16 make sure the stores were getting the 17 quantities that they needed based on 18 their peer group." 19 Is that correct? 20 A. That is part of the 21 testimony. And then if you want to go 22 over and flip over to 202, we can walk 23 our way through some more of that. 24 Q. All right. What do you got</p>	<p>1 interest. They are cutting orders in 2 particular. The quote -- the quote 3 that's there. "The item will be reduced 4 to nonsuspicious levels in order to 5 prevent suspicious from being sent over 6 to the DC." 7 Q. It's your testimony that 8 Walgreens' practice in the time frame 9 that's addressed on Page 201 of cutting 10 orders supports your position that 11 Walgreens was trying not to classify 12 pharmacy orders as suspicious so as not 13 to disrupt product supply? 14 A. That is what I'm saying. 15 Q. Okay. 16 A. I think that's part of it. 17 You asked me for every section in here 18 that applies to that statement. 19 Q. Let me ask you this, 20 Mr. Whitelaw. Other than Ms. Polster and 21 the two clips of testimony that we 22 discussed, who else do you think 23 specifically at Walgreens devoted 24 substantial time and resources trying to</p>
Page 411	Page 413
<p>1 on Page 202? 2 A. The whole discussion about 3 flagged orders are not suspicious orders. 4 We can read the whole section if you'd 5 like to walk all the way through it. 6 Q. That's okay. I'm familiar 7 with it. It's your testimony that the 8 entire section entitled "Flagged Orders 9 Are Not Suspicious Orders," supports your 10 statement on Page 46 that Walgreens was 11 trying not to classify excessive pharmacy 12 orders as suspicious so as not to disrupt 13 product supply? 14 A. Yes. 15 Q. Anything else? 16 A. We can keep going, but I 17 think that's -- that pretty much covers 18 it. 19 Q. Well, I'd like to know 20 everything that covers it. 21 A. I'll keep -- I'll keep 22 reading through. It's your time. 23 I think you can go back to 24 Page 201. Talk about the order of</p>	<p>1 avoid classifying excessive pharmacy 2 orders as suspicious? 3 A. I can't give you a complete 4 list of people. 5 Q. Can you name anybody else, 6 other than Ms. Polster? 7 A. Again, I'd have to re-read 8 the whole section of the report. If 9 you'd like me to do that, I can go 10 through it for you -- for you now. 11 Q. You can't think of anybody 12 now without re-reading your entire 13 section on Walgreens? 14 MR. BOGLE: You can read 15 your report if you need to. 16 MS. SWIFT: No, I'm -- I'm 17 not -- that's not what I'm asking 18 him to do. I'm asking if he can 19 do it without re-reading his 20 report. If the answer is no, 21 that's fine. 22 THE WITNESS: There's not a 23 name that comes to mind. 24 BY MS. SWIFT:</p>

<p style="text-align: right;">Page 414</p> <p>1 Q. All right. Let's go back to 2 Page 46, please. 3 THE WITNESS: Can I have 4 Walgreens' notes? 5 MS. SWIFT: He's asked to 6 refer to his notes, I'm going to 7 ask again for production of the 8 notes on Walgreens. 9 MR. BOGLE: If he refers to 10 them, yeah. He hasn't referred to 11 them yet. 12 BY MS. SWIFT: 13 Q. Are those notes on Walgreens 14 that you're looking at, Mr. Whitelaw? 15 A. Yes, Counsel, they are. 16 Q. Are you, in fact, referring 17 to them at this moment? 18 MR. BOGLE: You haven't 19 asked him a question. 20 MS. SWIFT: I just asked him 21 a question. 22 MR. BOGLE: You've asked him 23 to refer to them? 24 MS. SWIFT: I asked him if</p>	<p style="text-align: right;">Page 416</p> <p>1 Walgreens' notes. 2 (Document marked for 3 identification as Exhibit 4 Whitelaw-12.) 5 BY MS. SWIFT: 6 Q. I'll hand them back to you 7 and we'll look at them at a break. How 8 about that? 9 A. I'm not sure where we are 10 right now. 11 Q. Yeah, I'm not surprised. 12 You asked for the notes or 13 your counsel handed you the notes I 14 believe after I'd asked you if you could 15 name anybody else at Walgreens other than 16 Ms. Polster who you claim devoted 17 substantial time and resources to 18 avoiding identifying suspicious orders. 19 And I'll ask again, now that 20 you've had a chance to refer to the 21 notes, whether you can name anybody else 22 at Walgreens who you think did that? 23 A. I would also add to that 24 collection, I mean let's go back to the</p>
<p style="text-align: right;">Page 415</p> <p>1 he's referring to them right now. 2 THE WITNESS: I'm looking at 3 them. 4 MS. SWIFT: May I please 5 have the notes? 6 MR. BOGLE: Sure. 7 MS. SWIFT: And I'm going to 8 go off the record to look at the 9 notes for two minutes. 10 THE VIDEOGRAPHER: Going off 11 the record -- 12 MR. BOGLE: We both have to 13 agree to go off the record. I'm 14 not agreeing to go off the record. 15 MS. SWIFT: Really? 16 MR. BOGLE: Mm-hmm. 17 He's keeping the copy. 18 MS. SWIFT: You're not going 19 to agree to go off the record to 20 look at the notes? 21 MR. BOGLE: Unh-unh. 22 MS. SWIFT: I'm going to 23 hand them -- I'm going to mark 24 them as Exhibit 12, these are the</p>	<p style="text-align: right;">Page 417</p> <p>1 back end -- back of the report, and we 2 can add the people who were responsible 3 for the actual programming in and of 4 itself. So, you know. 5 Q. If you turn to the very end 6 of the Walgreens section, I think I can 7 help you out. 8 A. Yep. 9 Q. It's Page 208. The very 10 last paragraph of the Walgreens section. 11 Are you there? 12 A. I am there. 13 Q. You say, "The crucial 14 employees, with responsibility for 15 shaping, maintaining, and operating 16 Walgreens' anti-diversion program (e.g. 17 Natasha Polster, Edward Bratton and Rex 18 Swords)." 19 Are those the people that 20 you believe devoted substantial time and 21 resources to avoiding the classification 22 of suspicious orders? 23 A. I believe they were -- they 24 were certainly some of the people that</p>

<p style="text-align: right;">Page 418</p> <p>1 were involved in it, yes.</p> <p>2 Q. Can you name any others?</p> <p>3 A. I don't have an exhaustive</p> <p>4 list for you, counsel.</p> <p>5 Q. You don't have a list in</p> <p>6 your notes?</p> <p>7 A. I have a list of people that</p> <p>8 I reference in this report, but I don't</p> <p>9 have a list --</p> <p>10 Q. Okay. We can move on.</p> <p>11 A. -- to be able to answer your</p> <p>12 question.</p> <p>13 Q. Go back to Page 46, please.</p> <p>14 A. Yep.</p> <p>15 Q. Do you think it is a</p> <p>16 conflict of interest for a chain pharmacy</p> <p>17 to operate distribution centers that ship</p> <p>18 medications to their own pharmacies?</p> <p>19 A. Do I think it's a conflict</p> <p>20 of interest?</p> <p>21 Q. Yes.</p> <p>22 A. Do I think -- do you want to</p> <p>23 define what you mean by conflict of</p> <p>24 interest?</p>	<p style="text-align: right;">Page 420</p> <p>1 excessive quantities, in other words you</p> <p>2 were not providing it to them, that's</p> <p>3 going to impact your bottom line as a</p> <p>4 company. And the company, obviously</p> <p>5 Walgreens, is in the business of making</p> <p>6 money.</p> <p>7 That is a conflict. Can it</p> <p>8 be mitigated? Potentially.</p> <p>9 Q. So I'll ask my question</p> <p>10 again. Do you think it is a conflict of</p> <p>11 interest for a chain pharmacy like</p> <p>12 Walgreens to operate distribution centers</p> <p>13 that at one point in time shipped</p> <p>14 medications to their own pharmacies?</p> <p>15 A. I think it presents an</p> <p>16 inherent conflict that can be, in fact,</p> <p>17 mitigated appropriately.</p> <p>18 Q. What is the basis of your</p> <p>19 belief that it is a conflict of interest</p> <p>20 for a chain pharmacy to ship medications</p> <p>21 to its own pharmacies via its own</p> <p>22 distribution centers?</p> <p>23 A. Well --</p> <p>24 MR. BOGLE: Objection.</p>
<p style="text-align: right;">Page 419</p> <p>1 Q. You don't know what a</p> <p>2 conflict of interest is?</p> <p>3 A. I know what a conflict of</p> <p>4 interest is. I'm asking what you mean in</p> <p>5 this context, Counsel.</p> <p>6 Q. Well, take a look at the --</p> <p>7 let's see, where is it? The second</p> <p>8 paragraph from the bottom on Page 46,</p> <p>9 after you talk about the folks at</p> <p>10 Walgreens you claim devoted a lot of time</p> <p>11 trying not to classify suspicious orders,</p> <p>12 the next sentence you have there says,</p> <p>13 "This constituted an inherent conflict of</p> <p>14 interest."</p> <p>15 Do you see that?</p> <p>16 A. I do.</p> <p>17 Q. What did you mean by that</p> <p>18 statement?</p> <p>19 A. What I meant by that</p> <p>20 statement is that if you were classifying</p> <p>21 various and sundry and reporting various</p> <p>22 and sundry orders as suspicious and you</p> <p>23 were taking action against pharmacies,</p> <p>24 your own in this case, that were ordering</p>	<p style="text-align: right;">Page 421</p> <p>1 Asked and answered.</p> <p>2 THE WITNESS: If we just</p> <p>3 walk through it logically, the</p> <p>4 people who are supposed to be the</p> <p>5 gatekeepers are, in fact, being --</p> <p>6 are, in fact, being incentivized</p> <p>7 by the company. And better the</p> <p>8 company does, the better the</p> <p>9 bonuses, et cetera. So it's --</p> <p>10 it's an inherent conflict to the</p> <p>11 company. You have the gatekeepers</p> <p>12 in that -- in a difficult</p> <p>13 position. I didn't say it's --</p> <p>14 that's a conflict position.</p> <p>15 You're holding the company for</p> <p>16 your job.</p> <p>17 BY MS. SWIFT:</p> <p>18 Q. Do you have any other basis</p> <p>19 or support for that opinion that you just</p> <p>20 articulated?</p> <p>21 A. I am not sure what you're</p> <p>22 looking for, Counsel.</p> <p>23 Q. Okay. We can move on.</p> <p>24 Do you understand -- strike</p>

<p style="text-align: right;">Page 422</p> <p>1 that.</p> <p>2 All right. In the eight</p> <p>3 paragraph in this section, is the last</p> <p>4 paragraph on Page 46, refers to your</p> <p>5 compliance maturity and program</p> <p>6 effectiveness scale.</p> <p>7 Do you see that?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. That's the Figure 2 on Page</p> <p>10 43 that my colleague asked you about</p> <p>11 earlier today, correct?</p> <p>12 A. That is correct.</p> <p>13 Q. Figure 2 on page 43, the</p> <p>14 maturity scale, that's the model that you</p> <p>15 made up for figuring out where in its</p> <p>16 maturity level or life span a company is</p> <p>17 with respect to compliance. Is that a</p> <p>18 roughly fair statement?</p> <p>19 MR. BOGLE: Object to form.</p> <p>20 THE WITNESS: No, I don't</p> <p>21 think it's a fair statement. It's</p> <p>22 something -- you're characterizing</p> <p>23 it as something that I made up.</p> <p>24 No, it's something that is in</p>	<p style="text-align: right;">Page 424</p> <p>1 anywhere in the world?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: I'm assuming I</p> <p>4 can Google it and find it.</p> <p>5 BY MS. SWIFT:</p> <p>6 Q. We tried. We couldn't.</p> <p>7 Have you -- have you done that and seen</p> <p>8 it used publicly somewhere?</p> <p>9 A. You know, actually I have.</p> <p>10 I actually was able to Google Google</p> <p>11 Images at one point, and it did come up.</p> <p>12 Not the exact same -- again, it's -- the</p> <p>13 compliance maturity model is usually</p> <p>14 adapted. Each individual consultant</p> <p>15 or -- does some adaptation. The words</p> <p>16 may be slightly different. But that</p> <p>17 curve that we are talking about, the</p> <p>18 basic four parameters, yeah, I've seen it</p> <p>19 before.</p> <p>20 Q. I believe you testified</p> <p>21 you've seen it used by people at Deloitte</p> <p>22 and PwC; is that correct?</p> <p>23 A. I've seen it from PwC. I</p> <p>24 have seen it from Deloitte, yes.</p>
<p style="text-align: right;">Page 423</p> <p>1 general use among compliance</p> <p>2 professionals and others out</p> <p>3 there.</p> <p>4 BY MS. SWIFT:</p> <p>5 Q. You said that earlier today</p> <p>6 as well, that you knew of others who had</p> <p>7 used the compliance maturity scale. Who</p> <p>8 else has used it?</p> <p>9 A. I have seen it in use in my</p> <p>10 time in Deloitte. I've seen it used by</p> <p>11 PwC. I've seen it used by a variety of</p> <p>12 different consultants and companies, even</p> <p>13 some of my fellow colleagues when I was</p> <p>14 an inhouse compliance officer used it</p> <p>15 within their own organizations.</p> <p>16 Q. I believe you testified that</p> <p>17 you created the compliance maturity</p> <p>18 scale; is that correct?</p> <p>19 A. No, I testified that I</p> <p>20 created this diagram that's in this</p> <p>21 document, was what I created.</p> <p>22 Q. Okay. Have you ever seen</p> <p>23 the compliance maturity and program</p> <p>24 effectiveness scale used publicly</p>	<p style="text-align: right;">Page 425</p> <p>1 Q. Have you seen it anywhere</p> <p>2 else?</p> <p>3 A. As I said, I seem to recall</p> <p>4 some of my colleagues inhouse at other</p> <p>5 companies using it, but I can't tell you</p> <p>6 which companies and when and where, no.</p> <p>7 Q. You say in that paragraph on</p> <p>8 Page 46 that the two chain pharmacies are</p> <p>9 barely starting into the foundational</p> <p>10 level of the maturity scale, correct?</p> <p>11 A. That's what I say.</p> <p>12 Q. And if there were a remedial</p> <p>13 level, that's where they would be,</p> <p>14 correct?</p> <p>15 A. That was my statement, yes.</p> <p>16 Q. Okay. I understand that you</p> <p>17 don't have a scoring method or a point</p> <p>18 system for placing the pharmacies on your</p> <p>19 maturity scale. You said it today, it</p> <p>20 was more of a qualitative assessment. Is</p> <p>21 that right?</p> <p>22 A. That's fair.</p> <p>23 Q. Are both of the chain</p> <p>24 pharmacies that you looked at in the same</p>

<p style="text-align: right;">Page 426</p> <p>1 spot on the nonexistent remedial level of  2 the maturity scale?  3 A. Again, I'd say by and large,  4 yes.  5 Q. How can we tell that from  6 your report? I mean, where do we look in  7 your report to determine how far  8 Walgreens is from making its way onto the  9 foundational level of the compliance  10 maturity scale?  11 A. I didn't put you -- I didn't  12 put it on a graph, Counselor.  13 Q. That's why I'm asking the  14 question, sir.  15 A. No, I did not put it on a  16 graph.  17 Q. And so how are we supposed  18 to know from your report how far off the  19 scale we are?  20 A. I think you're missing the  21 point. Is you're not even moving to the  22 right-hand side of the scale, Counselor.  23 You're not even halfway to moving toward  24 an effective compliance program. You're</p>	<p style="text-align: right;">Page 428</p> <p>1 understand how I'm supposed to know where  2 you think we actually are.  3 A. I think I told you where I  4 think you actually are.  5 Q. But there's -- as you said a  6 moment ago, there's no graph or chart  7 that shows where Walgreens falls with  8 respect to the compliance maturity scale,  9 correct? That's not in the report?  10 A. There is no point on the  11 graph that I put Walgreens on, if that's  12 what you're asking, Counselor, no.  13 Q. Turn if you would, please,  14 to Page 183, which is the start of the  15 Walgreens section.  16 A. I'm here.  17 Q. I notice you -- the heading  18 on this Section 13 is "Walgreens Boots  19 Alliance." Is that correct?  20 A. Correct.  21 Q. The focus of the first  22 several paragraphs is also on Walgreens  23 Boots Alliance, right?  24 A. And Walgreens too. It's a</p>
<p style="text-align: right;">Page 427</p> <p>1 sitting at the left-hand edge. I think  2 you are overcharacterizing it.  3 Q. I understand that's your  4 position, sir. And I'm just trying to  5 get an understanding of your opinions.  6 And what I would like to know is, how,  7 from your report, am I supposed to  8 determine how far off to the left-hand  9 side of the scale Walgreens is supposed  10 to be?  11 A. And I guess what I'm trying  12 to say to you is I'm not sure that being  13 off to the left or how far off, if it's  14 one inch or three inches. I think you're  15 missing the point. You shouldn't be off  16 to the left-hand side at all. You should  17 be more towards the middle, to the  18 right-hand side of the graph. That's the  19 point.  20 Q. I understand that's your  21 position, sir. My question is coming  22 from a different place. I'm not asking  23 right now what you think we should have  24 done differently. I'm just trying to</p>	<p style="text-align: right;">Page 429</p> <p>1 history of your store, of the store and  2 the company.  3 Q. But you note in Footnote  4 1051 that Walgreens Boots Alliance is not  5 a defendant in this case, correct?  6 A. That's correct.  7 Q. Walgreen Co. and Walgreen  8 Eastern Co. are the defendants in these  9 cases, correct?  10 A. That's correct, Counselor.  11 Q. Do you know whether  12 Walgreens Boots Alliance ever distributed  13 opioid pain medications to any Walgreens  14 pharmacy?  15 A. During the time period that  16 we were looking at?  17 Q. At any point in time.  18 A. No, Counselor, I don't.  19 Q. Did you check?  20 A. No, I can't say I did.  21 Q. You cite various figures for  22 Walgreens Boots Alliance on Page 183 of  23 your report, correct, sir?  24 A. I do.</p>



<p style="text-align: right;">Page 430</p> <p>1 Q. You don't cite any of those 2 same figures for Walgreen Co., right? 3 A. No, I don't. 4 Q. You also don't cite any of 5 those same figures for Walgreen Eastern 6 Co., correct? 7 A. You are correct, I do not 8 cite separate figures for the 6A areas. 9 Q. You says that Walgreens 10 Boots Alliance maintains a pharmaceutical 11 wholesale and distribution network that 12 includes over 390 distribution centers, 13 correct? 14 A. Yes, that's what I say. 15 Q. Turn to Page 184, please. 16 In the third paragraph of that page, you 17 see the paragraph that starts, "By 2012"? 18 Are you with me? 19 A. Yes, I see it. 20 Q. You note there that 21 Walgreens, the defendant in these cases, 22 only had 13 distribution centers 23 registered to distribute controlled 24 substances, correct?</p>	<p style="text-align: right;">Page 432</p> <p>1 go through the document I can tell you 2 where I found it. 3 Q. You -- you noted in that 4 same paragraph that only three of 5 Walgreens distribution centers ever 6 handled Schedule II controlled 7 substances, correct? 8 A. Yes. 9 Q. Turn to Page 185 please. 10 You understand that Walgreens stopped 11 distributing all controlled substances 12 into Ohio in 2013, right, sir? 13 A. All controlled substances 14 into Ohio? I understand they stopped 15 with Schedule IIs in 2013, that was by 16 the end of October when it was 17 reclassified, 2014 was when the actual 18 stop date was for everything. 19 Q. So as far as your 20 understanding is though, Walgreens hasn't 21 distributed any type of opioid into Ohio 22 for at least five years, is that fair? 23 A. I would say that that is 24 fair.</p>
<p style="text-align: right;">Page 431</p> <p>1 A. Yes. 2 Q. Did you know that only five 3 of those distribution centers ever 4 distributed opioid pain medication into 5 either Summit or Cuyahoga County? 6 A. I knew there were three. I 7 didn't know necessarily there were five. 8 I know three of them. 9 Q. Did you look into that one 10 way or the other to see how many 11 distribution centers distributed into 12 Summit or Cuyahoga County? 13 A. I believe I did. But can't 14 exactly remember -- I remember looking 15 into asking where the primary was and 16 that's Perrysburg. But beyond that, I 17 don't remember. 18 Q. What's the basis of your 19 testimony that Perrysburg was the primary 20 distribution center? Just because it was 21 in Ohio? 22 A. No, I believe I -- I believe 23 it's in the Footnote 1068. But I'd have 24 to look at the document. If you want to</p>	<p style="text-align: right;">Page 433</p> <p>1 Q. You don't have any opinion 2 about Walgreens' suspicious order 3 monitoring program after that point in 4 time, correct, sir? 5 A. My examination ended with 6 the reclassification of hydrocodone in 7 October 2014. 8 Q. On Page 185 you've got a 9 section that starts "Executive Summary." 10 Do you see that? 11 A. I do. 12 Q. And you say in the first 13 sentence, "The overall theme to the 14 Walgreens' controlled substances 15 compliance program is too little too 16 late," correct? 17 A. That's what I saw. 18 Q. How long should it take to 19 develop a suspicious order monitoring 20 program? 21 MR. BOGLE: Object to form. 22 THE WITNESS: Are we talking 23 a hypothetical situation? From 24 where and which point? I'm not</p>

Page 434

1 sure what you're looking for,  
2 Counsel.  
3 BY MS. SWIFT:  
4 Q. I'm just asking in general.  
5 Can you tell me how long it -- it is  
6 supposed to take to develop a suspicious  
7 order monitoring program?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: Well, I can  
10 tell you how long it takes to put  
11 in a regular compliance program.  
12 It's anywhere from six to  
13 12 months normally. But again,  
14 the comment I'm making here is you  
15 were distributing -- Walgreens was  
16 distributing opioids well before  
17 it was trying to do significant  
18 changes to its program in 2008 and  
19 2009. That's the -- and it  
20 finally doesn't do -- you know, it  
21 finally gets -- it's working on  
22 it, and then in 2014 you're not  
23 doing it anymore at all.  
24 BY MS. SWIFT:

Page 435

1 Q. You said you could tell me  
2 how long it takes to put in a regular  
3 compliance program. Does that mean you  
4 can't tell me how long it should take to  
5 put it together --  
6 A. It's going to vary by the --  
7 it's going to vary --  
8 Q. I didn't finish my question.  
9 A. Sorry.  
10 Q. You said you can tell me how  
11 long it takes to put in a regular  
12 compliance program. Does that mean you  
13 can't tell me how long it would take to  
14 put together a suspicious order  
15 monitoring program?  
16 A. Without more details in the  
17 company, its structure, its resources and  
18 all the other components, no, I can't  
19 tell you that.  
20 Q. Does it depend on the  
21 company's business model?  
22 A. It depend -- that's a  
23 factor.  
24 Q. Does it depend on how many

Page 436

1 customers the company has?  
2 A. That could be a factor.  
3 Q. Does it depend on what kind  
4 of customers the company has?  
5 A. Again, could be a factor.  
6 Q. You don't provide an opinion  
7 on how long it should take to develop a  
8 suspicious order monitoring program in  
9 your report, correct, sir, an actual  
10 amount of time?  
11 A. An actual timeline.  
12 Q. Correct.  
13 A. No, I do not.  
14 Q. Is the time that it takes to  
15 develop a suspicious order monitoring  
16 program one of the factors you consider  
17 in your compliance maturity scale?  
18 A. The overall time frame? I'm  
19 not sure I understand the -- the  
20 question, Counsel.  
21 Q. Yeah. I'm just asking if  
22 whether the -- the amount of time it  
23 takes to develop a suspicious order  
24 monitoring program, is that something

Page 437

1 that you consider in rating companies on  
2 your compliance maturity scale?  
3 MR. BOGLE: Object to form.  
4 THE WITNESS: Again, it  
5 would depend on the factor -- if  
6 we are talking about you knew the  
7 regulations were a certain point  
8 and then it took you years to do  
9 it, yes.  
10 If we are talking -- again,  
11 it's a quantitative assessment.  
12 If you're asking me am I looking  
13 at a specific timeline.  
14 BY MS. SWIFT:  
15 Q. What I'm trying to get at  
16 is, we've got this scale --  
17 A. Right.  
18 Q. -- on Page 43 and --  
19 MR. BOGLE: Wait until she  
20 finishes.  
21 BY MS. SWIFT:  
22 Q. -- you know, you know, I'm  
23 wondering if a company takes six years to  
24 develop their suspicious order monitoring

<p style="text-align: right;">Page 438</p> <p>1 program, does that put them one place on 2 the scale, whereas if they took three 3 years it puts them something at someplace 4 else on the scale. 5 Is that the kind of thing 6 that you did when you were rating us on 7 your maturity scale? 8 A. I wouldn't say I rated you 9 on -- I wouldn't rate -- rated you 10 overall on the amount of time it took you 11 to get from A to B. 12 What I rated -- would have 13 rated you on for example, is if you're 14 trying to make a change and you know 15 you're trying to make a change and it's 16 taking you five years to make the change 17 that you knew -- you already said you 18 wanted to make. 19 Q. Okay. I don't understand 20 your answer. 21 You started off by saying 22 you wouldn't have rated us overall on the 23 amount of time -- 24 A. On the total time. I'm</p>	<p style="text-align: right;">Page 440</p> <p>1 the points where you think Walgreens took 2 too long to fix a gap in its system? 3 A. And again, I'm answering you 4 honestly, Counsel. I looked at a lot of 5 stuff. The document is 300 pages. If 6 you want a precise answer, I'm going to 7 need time to review the report. 8 Q. Well, let me ask it this 9 way. If there's an analysis that you did 10 laying out all the points where you think 11 it took us too much time to fix a gap, 12 I'll find that in the Walgreens section 13 of the report? 14 A. It should be in the section. 15 Q. All right. Take a look at 16 Page 186 if you would, please. 17 And actually, the lead-in to 18 it is at the bottom of 185. Sorry about 19 that. 20 The last sentence on 185 21 says, "Some of the key contributing 22 factors to this 'too little too late' 23 approach and the failure of Walgreens to 24 take its corporate anti-diversion</p>
<p style="text-align: right;">Page 439</p> <p>1 not -- I'm not looking at a total time 2 scale. What I'm saying to you is a 3 factor that I would have considered in 4 where you are on addressing compliance in 5 an effective manner would be if you know 6 you have a gap, how long is that gap open 7 before you actually try to close it or 8 before you actually get it closed. 9 Q. You haven't provided any 10 analysis in your report laying out the 11 points where you think Walgreens took too 12 long to fix a gap, correct, sir? 13 MR. BOGLE: Object to form. 14 THE WITNESS: I have to go 15 back -- I have to go back and read 16 the whole section again. If you'd 17 like we can do that. 18 BY MS. SWIFT: 19 Q. Well, we are going to be 20 short on time at a certain point. I'm 21 just asking, if sitting here today, 22 without re-reading again the Walgreens 23 section, can you tell me, you didn't do 24 any analysis in your report laying out</p>	<p style="text-align: right;">Page 441</p> <p>1 obligations seriously include," and then 2 on Page 186 we get three bullets, 3 correct? 4 A. That's correct. 5 Q. You say this is some of the 6 key contributing factors. Did you leave 7 any contributing factors out? 8 A. Not of the entire section. 9 Are you asking of the executive section? 10 Q. I'm -- I'm trying to get a 11 handle on how the section is organized. 12 A. Sure. 13 Q. And this executive summary 14 section reads as though it is an 15 executive summary summarizing what 16 follows. Is that fair? 17 A. That's a fair assessment, 18 yes. 19 Q. And what I want to know is 20 whether these three bullet lists are all 21 of your contributing factors, or if they 22 are, as you say, only some of them? Did 23 that make sense? 24 A. Yes, Counselor, it does.</p>

Page 442

1 What I would say is they are the major  
2 contributing factors. I would not say  
3 it's a complete and exhaustive list.  
4 Q. What contributing factors  
5 did you leave off of the bullet list on  
6 Page 186?  
7 A. Again, I'm going to have to  
8 go through the whole report again and  
9 read it again to refresh my memory to get  
10 you a list for you.  
11 Q. You can't tell me a single  
12 contributing factor that you left off the  
13 list?  
14 A. I can't tell you without  
15 reading the section again, no.  
16 Q. How many hours did you say  
17 that you've worked on this case, sir?  
18 A. Oh, I said I worked on this  
19 case at the moment, almost, what did I  
20 say, almost 2,000 hours, somewhere in  
21 there.  
22 Q. And can you remind me how  
23 much you've billed to date?  
24 A. A little over \$400,000.

Page 443

1 Q. A little over \$400,000 since  
2 fall of 2018; is that fair?  
3 A. November 2018.  
4 Q. A little over \$400,000 in  
5 the past six months?  
6 A. Yes.  
7 Q. And you can't tell me  
8 whether you left off any of the  
9 contributing factors to your opinions  
10 against Walgreens?  
11 MR. BOGLE: Objection.  
12 Asked and answered.  
13 THE WITNESS: You asked me.  
14 And, again, I'm not sure I -- the  
15 question has changed. So can we  
16 go back and --  
17 BY MS. SWIFT:  
18 Q. I'll re-ask the question.  
19 A. Thank you.  
20 Q. You've got three  
21 contributing factors that you say  
22 contribute to the too little too late  
23 approach and the failure of Walgreens to  
24 take its corporate anti-diversion

Page 444

1 obligations seriously.  
2 And I understand from your  
3 testimony so far, that these three  
4 factors are not all of the factors, that  
5 there are others that you left off of  
6 this bullet list. I just want to know  
7 what you left off the list.  
8 A. And again, I'm trying to  
9 tell you honestly. I'll tell you, what  
10 comes to mind -- and I can't give you an  
11 exhaustive list, Counselor -- comes to  
12 mind. You had policies and procedures.  
13 You didn't follow them. You're supposed  
14 to be doing due diligence, and you didn't  
15 do a good job of the documentation  
16 throughout. That's -- that's something  
17 that repeats throughout.  
18 Q. Okay.  
19 A. That's in there and  
20 discussed in details in various sections.  
21 MR. BOGLE: I could use a  
22 break. We've been a little over  
23 an hour.  
24 THE WITNESS: As could I.

Page 445

1 MR. BOGLE: Good time for a  
2 break?  
3 THE VIDEOGRAPHER: Going off  
4 the record. 6:06 p.m.  
5 (Short break.)  
6 THE VIDEOGRAPHER: Back on  
7 the record at 6:20 p.m.  
8 BY MS. SWIFT:  
9 Q. Mr. Whitelaw, do you have  
10 Exhibit 12, your Walgreens notes in front  
11 of you?  
12 A. Yes, Counselor, I do.  
13 Q. Is that your handwriting?  
14 A. Yes, actually, it is.  
15 Q. Did you take these notes  
16 exclusively when you were reviewing  
17 documents and testimony? And what I mean  
18 by that is I'm trying -- did you -- did  
19 any of these notes -- were these notes  
20 that you took while you had conversations  
21 with Mr. Rafalski?  
22 A. No, Counselor, they were  
23 not.  
24 Q. Okay. Take a look if you

<p style="text-align: right;">Page 446</p> <p>1 would please, sir, at -- I think it's the 2 third page. 3 MR. BOGLE: Sorry, you said 4 that you had other copies? 5 MS. SWIFT: I handed them 6 out, sorry. 7 BY MS. SWIFT: 8 Q. The third page that says, 9 "Flagged orders were not suspicious," at 10 the top of it. 11 Do you see that? 12 A. I'm not sure I'm on the 13 right page. 14 Q. I'm wondering if I'm missing 15 a page. 16 A. I'm just trying to -- 17 Q. I think it's the fourth 18 page. My apologies. 19 A. Flagged order -- yeah, I got 20 it. 21 Q. It says "Flagged orders were 22 not suspicious" at the top, correct? 23 A. That's what it says. 24 Q. Immediately under that, it</p>	<p style="text-align: right;">Page 448</p> <p>1 legal obligation to maintain a suspicious 2 order monitoring program under the DEA's 3 regulations? 4 A. Well, I would say to you, 5 Counselor, I would phrase it in a 6 slightly different way. They were no 7 longer a distributor. So as a 8 distributor, not distributing controlled 9 substances, they didn't have to come into 10 compliance with the distributor 11 requirements of the Controlled Substances 12 Act. 13 Q. You can set the notes aside 14 for now, sir. 15 A. Okay. 16 Q. All right. Turning back to 17 the three bullet points on Page 186, I 18 believe you told -- 19 A. Hang on a second. 20 Q. Sure. 21 A. Let me get to where you're 22 going. Yes, I'm here. 23 Q. I believe you told me that 24 these three bullet points, roughly</p>
<p style="text-align: right;">Page 447</p> <p>1 says, "No pharmacy manager or pharmacist 2 doing anything nefarious," correct? 3 A. Yes. 4 Q. And then there's another 5 section below that that starts, "Outside 6 distributors." 7 Do you see that? 8 A. Mm-hmm. I do see it. 9 Q. The second bullet under that 10 section says, "Not Walgreens' problem 11 because other distributors had own SOM 12 system," correct? 13 A. Correct. 14 Q. I believe you told me a few 15 minutes ago that you have no opinions 16 about Walgreens suspicious order 17 monitoring program after Walgreens 18 stopped distributing controlled 19 substances, correct? 20 A. That's what I believe I told 21 you, yes. 22 Q. Is that because after 23 Walgreens stopped distributing controlled 24 substances, Walgreens no longer had a</p>	<p style="text-align: right;">Page 449</p> <p>1 speaking, are an executive summary of the 2 section of the report on Walgreens that 3 follows, correct? 4 A. I would say the executive 5 summary in the Walgreens section is the 6 executive summary for Walgreens, and then 7 details follow in the report, yeah. 8 Q. Do the three bullet points 9 summarize the section on Walgreens at a 10 high level? 11 A. I think they're a high level 12 overview, yes. 13 Q. I'd like to know how each of 14 these three factors affected your 15 assessment of Walgreens' compliance 16 program, okay. I'll ask you some 17 questions. But I just want to orient you 18 a little bit. 19 A. Okay. I think I got your 20 orientation. 21 Q. Are any of the three factors 22 that appear in the executive summary more 23 important than the other two for your 24 assessment?</p>



Page 450

1 A. No. They're not in --  
 2 they're not in rank order, if that's what  
 3 you're asking.  
 4 Q. That was my very next  
 5 question.  
 6 And I take it from your  
 7 previous testimony you did not assign  
 8 points to each factor or anything like  
 9 that?  
 10 A. No, I didn't.  
 11 Q. The first factor is singular  
 12 retail focus, correct?  
 13 A. Correct.  
 14 Q. You say, "Walgreens' efforts  
 15 to manage controlled substances  
 16 compliance focused primarily on ensuring  
 17 its anti-diversion program did not  
 18 impinge on the retail stores' ability to  
 19 obtain the volume of opioid products that  
 20 the stores requested," correct?  
 21 A. That's what I have there,  
 22 yes.  
 23 Q. And then you've also got a  
 24 quotation in here from Ms. Polster again

Page 451

1 about, "You've got to take care of the  
 2 patients," right?  
 3 A. Correct.  
 4 Q. Is it your opinion that  
 5 pharmacies should not take care of their  
 6 patients?  
 7 MR. BOGLE: Object to form.  
 8 THE WITNESS: Counselor,  
 9 it's not my opinion that  
 10 pharmacies should not take care of  
 11 their patients. My opinion here,  
 12 and why this is offered, is that  
 13 you can't walk away from your  
 14 requirements under the Controlled  
 15 Substances Act as a distributor by  
 16 simply trying to make -- by simply  
 17 using "we've got to take care of  
 18 the patients" as a mantra for  
 19 noncompliance. That's what I'm  
 20 saying.  
 21 BY MS. SWIFT:  
 22 Q. Is it your opinion that,  
 23 although you can't walk away from your  
 24 regulatory requirements, you can walk

Page 452

1 away from the patients?  
 2 A. I did not say --  
 3 MR. BOGLE: Object to form.  
 4 THE WITNESS: No, I did not  
 5 say that.  
 6 BY MS. SWIFT:  
 7 Q. It's important for people  
 8 with legitimate medical needs to be able  
 9 to get their medication, right, sir?  
 10 A. Yes, it's important.  
 11 Q. The second factor that you  
 12 list is lack of time, attention and  
 13 resources, correct?  
 14 A. I talk to it, yes.  
 15 Q. You say that "the team  
 16 charged with controlled substances  
 17 compliance did not appreciate that  
 18 opioids were not 'widgets,'" correct,  
 19 sir?  
 20 A. That is a statement that I  
 21 have in my report, yes.  
 22 Q. And you've got widgets in  
 23 quotation marks, marks, right, sir?  
 24 A. Mm-hmm.

Page 453

1 Q. I noticed later on in the  
 2 Walgreens section you refer to one of the  
 3 Walgreens' employee's deposition  
 4 testimony where the word widgets was  
 5 used. Is that the basis --  
 6 A. That is a partial --  
 7 Q. -- of the statement?  
 8 A. That is the partial basis of  
 9 that statement.  
 10 Q. Is there another basis for  
 11 the -- the statement that Walgreens did  
 12 not appreciate that opioids were not  
 13 widgets?  
 14 A. I think if you look at the  
 15 way Walgreens approached the controlled  
 16 substances obligations overall, they lost  
 17 sight of the fact that they were dealing  
 18 with very dangerous products, and as a  
 19 result they simply became widgets.  
 20 It's a lot like -- akin to a  
 21 bank teller that starts to see money as  
 22 being nothing more than dirty paper.  
 23 It's the same sort of concept here.  
 24 Q. I think maybe my question

Page 454

1 wasn't clear. When I'm asking you for  
2 the basis of a statement in your report,  
3 what I'm looking for is a document or  
4 some testimony or something else that --  
5 A. I'm looking --  
6 Q. -- that you're using to  
7 support the statement. Not a further  
8 explanation of the statement. Does that  
9 make sense, sir?  
10 A. I think I understand you,  
11 Counselor.  
12 Q. And so my question is  
13 whether there's any other support for the  
14 widgets statement other than the  
15 testimony from the Walgreens employee who  
16 used the word widgets?  
17 A. And I'm going to tell you  
18 that I can't point you to a specific  
19 document. I reviewed a lot of documents  
20 in the case of Walgreens. And I think  
21 you have to take the report in the  
22 totality in which it is offered.  
23 So you're looking for a  
24 specific, and I'm trying to tell you you

Page 455

1 need to look at the whole.  
2 Q. But to the extent that there  
3 is any additional support, we're going to  
4 find it in the footnotes in the Walgreens  
5 section?  
6 A. I think you're going to find  
7 it in the Walgreens report, yes. And in  
8 my reliance materials as well.  
9 Q. Well, now before we were  
10 talking about the footnotes. And my  
11 understanding was that the footnotes are  
12 the specific support for those statements  
13 that are made in the given sections; is  
14 that fair?  
15 MR. BOGLE: Object to form.  
16 THE WITNESS: They are a  
17 good source of support. I  
18 wouldn't say they are the only  
19 level of support. Don't forget, I  
20 have the 30 years of experience  
21 doing -- doing this. So my  
22 experience comes into play there.  
23 You can't footnote that.  
24 BY MS. SWIFT:

Page 456

1 Q. Understood. And what I'm  
2 talking -- and that's fair.  
3 Setting aside your 30 years  
4 of experience, when you've got a specific  
5 document or a piece of testimony,  
6 something you can actually put in a  
7 footnote, you did that, right, sir?  
8 A. When I had something that  
9 actually was good supportive evidence for  
10 the point I was making and I put it in  
11 the footnotes, tried to make them as  
12 complete as possible, yes.  
13 Q. The third factor that you  
14 provide on Page 186 is overreliance on  
15 technology, correct, sir?  
16 A. That is correct, ma'am.  
17 Q. Now, you're not saying that  
18 Walgreens should have done its suspicious  
19 order monitoring manually for 8,000  
20 stores, are you, sir?  
21 A. No, Counselor, I'm not.  
22 Q. Okay. Technology is a  
23 necessary part of a suspicious order  
24 monitoring for a distributor like

Page 457

1 Walgreens, wouldn't you agree with that,  
2 sir?  
3 A. Given the size and factors  
4 and number of stores that you're  
5 responsible for, yes. I would say  
6 tech -- you're going to need the  
7 assistance of technology.  
8 Q. The bottom paragraph under  
9 those three bullet points says, "When  
10 taken together, from 1998 to 2014,  
11 Walgreens' controlled substance  
12 compliance program was inadequate and in  
13 my opinion did not rise to the  
14 foundational level on the compliance,  
15 maturity, and program effectiveness  
16 model," correct?  
17 A. Yes, that's what it says.  
18 Q. Are you saying that  
19 Walgreens' failures on these three  
20 bullet-listed factors, that's what -- and  
21 I understand is explained in more detail  
22 later in the section on Walgreens.  
23 But what you're saying as I  
24 understand it, is that these three bullet

Page 458

1 points, these factors, are what led you  
2 to conclude that Walgreens did not rise  
3 to the foundational level on your  
4 maturity scale that appears on Page 43?  
5 MR. BOGLE: Object to form.  
6 THE WITNESS: I think what  
7 I'm trying to say, Counselor, is  
8 you have to read the whole section  
9 to get to that.  
10 I'm saying I drew out three  
11 broad themes that struck -- struck  
12 me as I worked my way through the  
13 Walgreens documents and testimony  
14 from this period in time. These  
15 are the three broad things that  
16 came, you know, that struck me --  
17 BY MS. SWIFT:  
18 Q. But in --  
19 A. -- and I felt were important  
20 to put.  
21 They are not the only things  
22 that would lead you to conclude that the  
23 program was ineffective.  
24 Q. Well, all right. But as I

Page 459

1 understand it, you can't help me  
2 understand what other missing factors  
3 there are from this page. I've got to go  
4 and -- and find that. But it will be in  
5 the Walgreens section, right?  
6 A. Well, hang on. I think I  
7 can generally help you, Counselor --  
8 Q. I -- I don't want you to do  
9 that right now. I'm just trying to --  
10 what I'm trying to figure out is, in  
11 terms of your methodology --  
12 A. Yeah.  
13 Q. -- these are, in broad  
14 strokes, the three factors that led you  
15 to conclude that we aren't even at the  
16 foundational level of the maturity scale,  
17 right?  
18 MR. BOGLE: Objection.  
19 Asked and answered.  
20 THE WITNESS: I would say  
21 they are three of the major  
22 factors that lead me to that  
23 position, yes.  
24 BY MS. SWIFT:

Page 460

1 Q. Okay. If we had done better  
2 on one of these three factors, would we  
3 have made our way onto the foundational  
4 level of the maturity scale?  
5 A. I'm not sure, Counselor.  
6 You have to look at the totality of the  
7 specifics to be able to try to answer  
8 that for you.  
9 Q. You can't tell me sitting  
10 here today, after working on this case  
11 for --  
12 A. I'd say --  
13 Q. -- almost six months,  
14 whether doing better on any one of these  
15 factors would have made it -- made us,  
16 you know, no longer remedial and onto the  
17 foundational level?  
18 A. You seem to be approaching  
19 this from the standpoint of it being a  
20 simple checklist. So if I do better on  
21 A, or if I do better on C, it gets me  
22 over the hump to being foundational.  
23 It's not -- compliance programs have to  
24 be looked at in a totality and in a

Page 461

1 whole, and that's exactly what I did.  
2 So I can't tell you that if  
3 you check a certain box on a certain  
4 piece of paper, that that's going to be  
5 the deciding factor to get you over the  
6 foundational level.  
7 Q. And that's not laid out  
8 anywhere in your report either, sir, is  
9 it, that, you know, if you had done X, Y,  
10 and Z, then you would have been at the  
11 foundational level?  
12 MR. BOGLE: Object to form.  
13 BY MS. SWIFT:  
14 Q. Your report doesn't say  
15 that, does it?  
16 MR. BOGLE: Object to form.  
17 THE WITNESS: I think if you  
18 looked at the -- if you look at  
19 the maturity model, you will see  
20 sort of the things that are  
21 considered when you look to say,  
22 do you fit in one of those  
23 buckets. I think it's there in  
24 the report in the beginning of the

<p style="text-align: right;">Page 462</p> <p>1 report.</p> <p>2 But again, if you're looking</p> <p>3 for, did I develop a distinctly --</p> <p>4 a distinct scorecard with -- with</p> <p>5 ratings, it's five points for</p> <p>6 this, ten points for that, no, I</p> <p>7 did not.</p> <p>8 BY MS. SWIFT:</p> <p>9 Q. And you didn't lay out</p> <p>10 anywhere in your report, here's what</p> <p>11 Walgreens could have done to make its way</p> <p>12 onto the foundational level of the</p> <p>13 maturity scale, correct?</p> <p>14 A. Actually, I do lay out at</p> <p>15 the beginning of the report in Section 6</p> <p>16 the attributes of what a good compliance</p> <p>17 program would look like. So if you read</p> <p>18 through that list and you match that up</p> <p>19 with what was missing, you can see how</p> <p>20 you can move up that scale, absolutely.</p> <p>21 Q. And it's your testimony that</p> <p>22 if we put the pages of attributes</p> <p>23 together with what you said in the</p> <p>24 Walgreens section, we'd be able to figure</p>	<p style="text-align: right;">Page 464</p> <p>1 it was we were supposed to do that would</p> <p>2 take us to the maturing level of the</p> <p>3 compliance -- of the maturity scale.</p> <p>4 Would that have meant that we were</p> <p>5 compliant with the Controlled Substances</p> <p>6 Act?</p> <p>7 A. Again, without having</p> <p>8 specifics, I can't give you a precise</p> <p>9 answer.</p> <p>10 Q. Okay. All right. On Page</p> <p>11 187, you start a discussion of three</p> <p>12 Walgreens stores, correct?</p> <p>13 A. Yep, there are three there.</p> <p>14 Q. In your three examples, you</p> <p>15 talk about actual orders those Walgreens</p> <p>16 pharmacies placed with a Walgreens</p> <p>17 distribution center, correct, sir?</p> <p>18 A. I talk about orders that</p> <p>19 were placed with the distribution center,</p> <p>20 yes.</p> <p>21 Q. Focusing first on Walgreens</p> <p>22 Store 3226, you point out some actual</p> <p>23 orders of oxycodone per month in three</p> <p>24 months of 2010, correct?</p>
<p style="text-align: right;">Page 463</p> <p>1 out how to place ourselves at any point</p> <p>2 along the scale?</p> <p>3 A. No. My testimony was that</p> <p>4 you would be able to see how you could</p> <p>5 move up the scale. I didn't say that you</p> <p>6 didn't do any particular one bucket or</p> <p>7 another.</p> <p>8 Q. If Walgreens had done</p> <p>9 whatever it was that we were supposed to</p> <p>10 do to make our way to the foundational</p> <p>11 level on your maturity scale, would that</p> <p>12 have meant we were compliant with the</p> <p>13 Controlled Substances Act?</p> <p>14 MR. BOGLE: Object to form.</p> <p>15 THE WITNESS: No, it</p> <p>16 wouldn't necessarily mean you were</p> <p>17 compliant with the Controlled</p> <p>18 Substances Act. It would mean</p> <p>19 that you had the beginnings of</p> <p>20 a -- you were starting on the</p> <p>21 journey to an effective compliance</p> <p>22 program.</p> <p>23 BY MS. SWIFT:</p> <p>24 Q. What if we had done whatever</p>	<p style="text-align: right;">Page 465</p> <p>1 A. I did.</p> <p>2 Q. Your point is that Walgreens</p> <p>3 needed to look at those orders to see</p> <p>4 what was going on at that store in order</p> <p>5 to determine whether diversion was</p> <p>6 occurring; is that fair?</p> <p>7 A. They needed to do due</p> <p>8 diligence on each of those orders to</p> <p>9 understand why they were above the</p> <p>10 thresholds. That is my testimony, yes.</p> <p>11 Q. You say that Store 3226's</p> <p>12 limit was 1,800 dosage units, based on a</p> <p>13 calculation that you've provided of 600</p> <p>14 base dosage units times Factor of 3.</p> <p>15 What's the basis of your</p> <p>16 statement that 1,800 dosage units of</p> <p>17 oxycodone was a limit for this store?</p> <p>18 A. I believe it's actually in</p> <p>19 the SOR report itself that's cited here.</p> <p>20 But again, to be able to confirm that for</p> <p>21 you, Counselor, I need to see the</p> <p>22 document. So if you'd like to show it to</p> <p>23 me, we can get there.</p> <p>24 Q. That's okay. Is it your</p>

Page 466

1 testimony that the docs -- the documents  
2 cited in Notes 1079 through 1081, those  
3 are the -- those are the basis for that  
4 statement? Is that fair? Or is it maybe  
5 just that first footnote?  
6 A. Again, you're asking me to  
7 opine on documents I can't -- I've looked  
8 at so many, I can't remember. So I can't  
9 tell you whether it's just this one or  
10 multiple documents. I need to see the  
11 documents again. If you'd like to show  
12 them to me, I can probably answer your  
13 question with some more precision.  
14 Q. Is it your testimony that  
15 you can't talk about any document that's  
16 not in front of you?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: It's my  
19 testimony that I've looked at so  
20 many documents, and accuracy is so  
21 important as you're stressing  
22 right here with me right now, that  
23 in order to be accurate I need to  
24 see the document. I think that's

Page 467

1 only fair considering the amount  
2 of work that I've done and the  
3 amount of, you know, documents  
4 that have been reviewed and size  
5 of the report, et cetera.  
6 BY MS. SWIFT:  
7 Q. Let's take a look at Store  
8 3314, you include a table purporting to  
9 show this store's oxycodone purchases by  
10 year between 2006 and 2010, correct?  
11 A. That's what I have here,  
12 yes.  
13 Q. And for the source of that  
14 table, you cite an Exhibit 13 to Eric  
15 Stahmann's deposition, correct?  
16 A. I believe that's correct.  
17 Q. Did you read Mr. Stahmann's  
18 deposition transcript?  
19 A. I reviewed Mr. Stahmann's --  
20 certain deposition transcripts. Yes.  
21 Q. Do you know what Exhibit 13  
22 is?  
23 A. Again, without seeing the  
24 document to refresh my recollection, all

Page 468

1 I can go by is what I cited to in my  
2 report here, opioid shipments to this  
3 particular store by the distributor  
4 being -- by distributor for 2006 to 2014.  
5 That's what it purports to be.  
6 Q. I take it from the citation  
7 to Exhibit 13 of Mr. Stahmann's  
8 deposition that you looked at a document  
9 with an exhibit sticker on it from his  
10 deposition?  
11 A. Yeah, it would have been  
12 digital, but yes.  
13 Q. Did you do anything to check  
14 the accuracy of the information in  
15 Exhibit 13 to Mr. Stahmann's deposition?  
16 A. Do you mean did I  
17 independently go to source documents  
18 behind 13?  
19 Q. Mm-hmm.  
20 A. No.  
21 Q. Did you do anything to  
22 determine who created the spreadsheet  
23 that appeared in Exhibit 13?  
24 A. No.

Page 469

1 Q. Turn to the next page. I'll  
2 ask you a question or two about Store  
3 12444. You say in that paragraph, that,  
4 "Despite the red flag indications of  
5 potential diversion, an increase in this  
6 store's allotment of oxycodone was  
7 approved."  
8 What red flags of potential  
9 diversion are you talking about?  
10 A. Well, one, you have the fact  
11 that they're working with a pain  
12 management clinic, which is potential red  
13 flag. Again, these are all potentials.  
14 You're looking at a fairly high dosage  
15 level compared to other stores.  
16 What I'm saying here is  
17 looking at this and just eyeballing it  
18 and approving it in 24 hours, there  
19 needed to be more due diligence done.  
20 That is the point.  
21 Q. So your point is 24 hours  
22 wasn't enough time to spend on due  
23 diligence?  
24 A. What I'm saying is I didn't



Page 470

1 see any evidence of anything looked at  
2 beyond just the threshold increase  
3 request. I didn't see anything else in  
4 the override. I didn't see anything that  
5 showed that there were any background  
6 documentation, that there was any  
7 effective due diligence done to  
8 understand the reason for the increase.  
9 Q. Well, you say that the  
10 rationale provided was that the store  
11 serves an emergency room, hospital, a  
12 pain management clinic, and hospice care,  
13 correct, sir?  
14 A. Yes, I did state that.  
15 Q. And you're not saying that  
16 instead of 24 hours, Walgreens should  
17 have spent 48 hours on due diligence or  
18 something some other specific period of  
19 time, right, sir?  
20 A. What I'm saying to you is  
21 that based on the timestamps and looking  
22 at the dates of approval, you did it  
23 within 24 hours. The problem -- the real  
24 underlying problem here is, I can't tell

Page 471

1 what the hell you looked at, other than  
2 just this one statement saying, you know,  
3 this is the reason why we need the  
4 increase.  
5 I don't see any background  
6 work that was done. I don't see any  
7 looking at the store's history, et  
8 cetera. The record is silent.  
9 Q. You would agree that a  
10 pharmacy that serves an emergency room, a  
11 hospital, a pain management clinic, and a  
12 hospice center probably has good reason  
13 to have a large number of opioid  
14 prescriptions, maybe larger than a  
15 pharmacy that didn't serve those sorts of  
16 needs?  
17 MR. BOGLE: Object to form.  
18 Calls for speculation.  
19 THE WITNESS: You're asking  
20 me to speculate?  
21 BY MS. SWIFT:  
22 Q. Is it your testimony that  
23 you don't know whether a -- whether a  
24 pharmacy that serves an emergency room, a

Page 472

1 hospital, a pain management clinic, and a  
2 hospice center, you don't know one way or  
3 the other, whether that pharmacy might  
4 need larger orders of opioids?  
5 MR. BOGLE: Object to form.  
6 THE WITNESS: Again, I can  
7 speculate. I'm not sure anybody  
8 can tell you with definitive. Is  
9 it a possibility and a factor to  
10 be considered? Yes. But again,  
11 as we've been stressing, there are  
12 multiple factors to be considered.  
13 And all I see is that's the only  
14 factor that was considered.  
15 BY MS. SWIFT:  
16 Q. And you can't say without  
17 speculating whether that would be a  
18 legitimate reason for a pharmacy to have  
19 a larger than normal order; is that fair?  
20 MR. BOGLE: Object to form.  
21 Misstates testimony.  
22 THE WITNESS: Without  
23 understanding all of the context  
24 around it and the due diligence

Page 473

1 that was done and -- and the  
2 customer history and all the other  
3 things for context, I'm looking at  
4 this in a vacuum. As I believe  
5 Walgreens was.  
6 BY MS. SWIFT:  
7 Q. Are all of the opinions that  
8 you have on these three Walgreens stores  
9 contained right here on these two pages?  
10 A. I'm not sure I'm  
11 understanding what you're asking me.  
12 Counselor, are you asking me do I  
13 reference the stores anywhere else in the  
14 report? I don't remember.  
15 Q. No. No, I'm not. I'm just  
16 asking you whether you're planning on  
17 coming to trial and saying anything else  
18 about these three stores besides what  
19 you've said in your report.  
20 A. As with everything else, if  
21 the facts and circumstances change, I  
22 reserve the right to amend my report.  
23 But at this present time, no, I do not.  
24 Q. You say at the top of

Page 474

1 Page 187 that these three stores are  
2 "just a few examples," right, sir?  
3 A. Yes, counselor, I did.  
4 Q. You don't discuss any other  
5 examples of Walgreens stores in your --  
6 in your report, correct?  
7 A. No, I used these as three  
8 examples.  
9 Q. Sorry, there's an ambiguity  
10 in the answer.  
11 Am I correct that there are  
12 no other Walgreens stores discussed in  
13 your report?  
14 A. I'd have to go through the  
15 report to say do I ever discuss yet any  
16 other Walgreens stores in my report to be  
17 absolutely certain.  
18 Q. If it's not discussed in the  
19 Walgreens section of the report, fair to  
20 say you're not going to offer an opinion  
21 about that Walgreens store at trial?  
22 A. I'm not planning to make any  
23 amendments to the report, unless the  
24 facts and circumstances change.

Page 475

1 Q. Did you consider any other  
2 example Walgreens stores in working on  
3 this case?  
4 A. Yes, I did.  
5 Q. Why didn't you include those  
6 in your report?  
7 A. Well, Counselor, I went with  
8 the audit theory that basically three  
9 points make a curve. You don't have to  
10 be exhaustive. And you don't have to  
11 list every single example of poor due  
12 diligence. These three are good examples  
13 of poor due diligence on -- on Walgreens'  
14 part.  
15 Q. How many Walgreens stores  
16 did you look at that you did not include  
17 in your report?  
18 A. I don't know off the top of  
19 my head.  
20 Q. Can you ballpark it?  
21 A. No, Counselor, I can't.  
22 Q. Was it more than five?  
23 A. Counselor, I can't ballpark  
24 it. You're asking me to remember what I

Page 476

1 looked at out of thousands of documents.  
2 Q. Well, I'm not asking you to  
3 remember what you looked at out of  
4 thousands of documents. I'm asking you  
5 to remember any other Walgreens store  
6 that you considered and decided not to  
7 include in your report.  
8 MR. BOGLE: Objection.  
9 Asked and answered.  
10 THE WITNESS: Counselor, I  
11 can't give you a number, I'm  
12 sorry.  
13 BY MS. SWIFT:  
14 Q. Take a look at Page 189,  
15 please.  
16 A. Yep.  
17 Q. At the end of  
18 Section 13.4.1, the last paragraph starts  
19 consequently.  
20 Do you see that? It's  
21 about --  
22 A. Yeah.  
23 Q. -- halfway down the page.  
24 A. Mm-hmm.

Page 477

1 Q. You say, "Consequently, from  
2 an inventory management perspective."  
3 And my question for you is, if you're  
4 looking at this from an inventory  
5 management perspective, does that mean  
6 you're not looking at it from a  
7 suspicious order monitoring perspective?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: I'm not sure I  
10 understand your question,  
11 Counselor.  
12 BY MS. SWIFT:  
13 Q. You -- you understand that  
14 inventory management is different from  
15 suspicious order monitoring, correct,  
16 sir?  
17 A. Yes, I know -- I know that  
18 it's different.  
19 Q. And what you're talking  
20 about in this section of your report is  
21 from an inventory management perspective,  
22 correct, sir?  
23 A. No. What I'm -- what I'm  
24 saying here, Counselor, is, I believe,

Page 478

1 again I'd love to re-read Mr. Murray's  
2 deposition. But my recollection is what  
3 I'm talking about here is that Mr. Murray  
4 was looking at suspicious order  
5 monitoring only from an inventory  
6 management perspective.  
7 Q. Are you sure that's what he  
8 was talking about, when he -- when he was  
9 saying a widget is a widget?  
10 A. I said -- Counselor, I would  
11 need to see the actual deposition.  
12 Q. I understand. I understand.  
13 You quote Ms. Polster again  
14 in this paragraph where she says, "The  
15 whole point behind it, the system, was to  
16 have simplicity."  
17 Do you see that?  
18 A. Yes, I do see that.  
19 Q. Is it your opinion that  
20 simplicity in an inventory management  
21 system is inconsistent with a company's  
22 anti-diversion obligations?  
23 MR. BOGLE: Object to form.  
24 THE WITNESS: No, Counselor,

Page 479

1 I'm not saying that at all.  
2 What I'm saying here is that  
3 if that is your sole goal -- the  
4 sole goal of a suspicious order  
5 monitoring system should be  
6 compliance, not necessarily  
7 simplicity. Now if you can get  
8 both simplicity and compliance,  
9 that's -- that's a great thing.  
10 But, making simplicity your  
11 primary focus over achieving  
12 compliance, that's not where you  
13 should be.  
14 BY MS. SWIFT:  
15 Q. And it's your testimony that  
16 this partial sentence from Ms. Polster's  
17 deposition means that her sole goal was  
18 to have simplicity; is that correct?  
19 A. No. I said primary goal,  
20 not sole goal.  
21 Q. But you're basing that on  
22 this partial sentence from Ms. Polster's  
23 deposition?  
24 A. That's one of the things I'm

Page 480

1 basing it on --  
2 MR. BOGLE: Objection to  
3 form. Asked and answered.  
4 THE WITNESS: -- plus all  
5 the other documents I've read and  
6 the entire context of reading --  
7 of working on this section. As  
8 well as my experience, Counselor.  
9 BY MS. SWIFT:  
10 Q. Is it your opinion that  
11 having simplicity in your inventory  
12 system means you can't focus on your  
13 anti-diversion obligations?  
14 MR. BOGLE: Object to form.  
15 THE WITNESS: I think I  
16 answered the question.  
17 I said if you put simplicity  
18 above compliance, that's the --  
19 that's the problem. But trying to  
20 get both, both -- as long as you  
21 achieve compliance and you can  
22 also achieve simplicity, that is  
23 not an inherently bad thing.  
24 BY MS. SWIFT:

Page 481

1 Q. The next section, 13.4.2,  
2 talks about codes of conduct, correct?  
3 A. It does.  
4 Q. You talk about a business  
5 ethics code and a pharmacy code, right?  
6 A. Yes, I do.  
7 Q. You understand that not all  
8 employees at Walgreens are pharmacists?  
9 A. Yes, I do understand that.  
10 Q. At Page 191 of the report  
11 you see -- you say -- this is at the  
12 beginning of the first full paragraph --  
13 "The maintenance of two separated and  
14 unlinked codes of conduct increases  
15 complexity and the likelihood that the  
16 two documents will become out of sync,"  
17 correct?  
18 A. I did write that and say  
19 that.  
20 Q. You're not saying that it's  
21 a violation of the Controlled Substances  
22 Act to have multiple codes of conduct  
23 that are out of sync with each other, are  
24 you, sir?

Page 482

1 MR. BOGLE: Object to form.  
2 THE WITNESS: No. What I'm  
3 saying is it is a problem from  
4 a -- from an effective compliance  
5 program standpoint to have  
6 multiple codes and policies that  
7 are out of sync with one another.  
8 BY MS. SWIFT:  
9 Q. It's also not a violation of  
10 the DEA's suspicious order monitoring  
11 program to have multiple codes of  
12 conduct, correct, sir?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Again,  
15 Counselor, we're not just looking  
16 at whether or not there's a  
17 violation of the Controlled  
18 Substances Act. The work I was  
19 asked to do was look at an  
20 effective corporate and controlled  
21 substance compliance program from  
22 standards that a reasonable and  
23 prudent company would use. And  
24 one thing that reasonable and

Page 483

1 prudent companies do is try to  
2 make sure they don't have policies  
3 and procedures that get out of  
4 sync because you have multiple  
5 different versions of a document.  
6 BY MS. SWIFT:  
7 Q. Fair to say, then, that a  
8 lot of the complaints you have about my  
9 client are not violations of the  
10 Controlled Substances Act?  
11 MR. BOGLE: Object to form.  
12 Misstates testimony.  
13 THE WITNESS: I don't think  
14 that's what I said, Counselor. I  
15 said my primary -- what I was  
16 looking at, and particularly in  
17 the case of this, are indicia of  
18 not having an effective program.  
19 Multiple documents in  
20 multiple different hands can get  
21 out of sync. And this was an  
22 example of just what can happen  
23 when you -- when that occurs.  
24 BY MS. SWIFT:

Page 484

1 Q. The next section starting on  
2 191 is titled "Organization."  
3 Do you see that?  
4 A. Yes, I do.  
5 Q. You -- I understand that you  
6 think Walgreens' organizational structure  
7 was substandard.  
8 Are you offering an opinion  
9 that the Controlled Substances Act  
10 requires Walgreens to have a particular  
11 organizational structure?  
12 MR. BOGLE: Object to form.  
13 THE WITNESS: I am offering  
14 an opinion that to have an  
15 effective compliance program, and  
16 that includes an effective  
17 anti-diversion program and  
18 anti-SOM -- effective SOM  
19 program --  
20 BY MS. SWIFT:  
21 Q. I'm sorry, sir. It's  
22 getting late, and I don't want to --  
23 MR. BOGLE: Whoa, whoa,  
24 whoa.

Page 485

1 MS. SWIFT: No, I'm sorry.  
2 He --  
3 MR. BOGLE: If you want to  
4 withdraw your question, that's  
5 fine.  
6 MS. SWIFT: I will --  
7 MR. BOGLE: He can -- he's  
8 going to finish his answer.  
9 MS. SWIFT: I will withdraw  
10 the question.  
11 MR. BOGLE: All right.  
12 Fine.  
13 BY MS. SWIFT:  
14 Q. And I'm going to ask you to  
15 listen to my question. I did not ask you  
16 whether -- whether your opinion was -- I  
17 didn't ask you about your opinion about  
18 an effective compliance program.  
19 I asked you whether you  
20 think the Controlled Substances Act  
21 requires Walgreens to have a particular  
22 organizational structure.  
23 A. I think I would answer that  
24 to you, Counselor, you are required to

Page 486

1 have an effective anti-diversion program.  
2 Part of looking at all the factors around  
3 what goes into an effective  
4 anti-diversion program would be, giving  
5 the people who are the gatekeepers  
6 sufficient power, empowering them, if we  
7 can use that overused word, and authority  
8 to make changes and to achieve compliance  
9 is an indicia of an effective program.  
10 Q. I don't understand if that's  
11 an answer to my question. Is that a yes,  
12 that the Controlled Substances Act  
13 requires a particular organizational  
14 structure?  
15 MR. BOGLE: Object to form.  
16 You can answer how you see  
17 fit. You don't have to say yes or  
18 no.  
19 THE WITNESS: As I said to  
20 you, I think having an empowered  
21 controlled substances program team  
22 is part of an indicia of an  
23 effective compliance program and  
24 effective anti-diversion program.

Page 487

1 BY MS. SWIFT:  
2 Q. Do you believe that  
3 Walgreens' organizational structure  
4 violated the Controlled Substances Act?  
5 MR. BOGLE: Objection.  
6 Asked and answered.  
7 BY MS. SWIFT:  
8 Q. Yes or no?  
9 MR. BOGLE: You don't have  
10 to say yes or no.  
11 THE WITNESS: I think I've  
12 answered your question as best I  
13 can, Counselor.  
14 MS. SWIFT: And I would just  
15 like to -- maybe you haven't seen  
16 Special Master Cohen's ruling from  
17 the Eagleman deposition.  
18 MR. BOGLE: You can't force  
19 him to say yes or no to all of  
20 your questions.  
21 MS. SWIFT: I'm not forcing  
22 him to do anything. I'm entitled  
23 to ask for a yes or no answer to a  
24 yes or no question.

Page 488

1 MR. BOGLE: He's entitled to  
2 answer the question however he  
3 sees fit.  
4 MS. SWIFT: Are you going  
5 to -- is it your position that I'm  
6 not entitled to ask for a yes or  
7 no answer?  
8 MR. BOGLE: You can ask --  
9 no, you can ask whatever you want.  
10 He just doesn't have to give it to  
11 you.  
12 MS. SWIFT: Are you going to  
13 flout Special Master Cohen's  
14 ruling that we are entitled to a  
15 yes or no answer?  
16 MR. BOGLE: I'm letting him  
17 answer the questions the way he  
18 sees fit, which means if he  
19 doesn't -- if he can't answer yes  
20 or no, he's not forced to answer a  
21 question a yes or no just because  
22 you say he is.  
23 BY MS. SWIFT:  
24 Q. Mr. Whitelaw, do you believe

Page 489

1 that it's a violation of the DEA's  
2 suspicious order monitoring regulation to  
3 be organized the way that Walgreens was  
4 organized in this time frame? Yes or no,  
5 please.  
6 MR. BOGLE: Objection.  
7 Asked and answered.  
8 Answer how you see fit.  
9 MS. SWIFT: I asked about  
10 the Controlled Substances Act  
11 before. Now I'm asking about the  
12 DEA suspicious order monitoring.  
13 THE WITNESS: I'm going to  
14 answer you the same way, Counsel.  
15 Because I'm going to go back to  
16 the point in my report, which is  
17 if you want to go back is to the  
18 front of the report and we'll talk  
19 about the Russian nesting dolls,  
20 we can spend 20 minutes on that  
21 and have that conversation.  
22 They're all part and parcel.  
23 It all fits together.  
24 And again, what I'm saying



<p style="text-align: right;">Page 490</p> <p>1 to you is, part of having an 2 effective program is that the 3 people who are the gatekeepers 4 have to have sufficient 5 empowerment and authority to carry 6 out the duties they've been 7 assigned. That is my opinion, 8 Counselor. 9 BY MS. SWIFT: 10 Q. With respect, I do not know 11 whether your opinion is that Walgreens' 12 organizational structure violated either 13 the Controlled Substances Act or the 14 DEA's suspicious order monitoring 15 regulation. I don't know the answer to 16 that question. Will you please answer 17 it? 18 A. I've answered it the best 19 way I can. 20 Q. Okay. Turning back to Page 21 186, please. I'm sorry. I misread my 22 own outline. 192, actually. And the 23 reason I started to take you back -- 24 well, it doesn't matter.</p>	<p style="text-align: right;">Page 492</p> <p>1 represented in an org chart from mid 2 2012," correct? 3 A. That's what I say. Yes. 4 Q. Is it your opinion that 5 spreading responsibility for controlled 6 substances compliance across multiple 7 departments is a violation of the 8 Controlled Substances Act? 9 A. No. Counselor, what I've 10 been saying all along is it's an indicia 11 of an ineffective program. What I'm 12 saying is that by spreading and diffusing 13 responsibility across, you're not 14 empowering the gatekeepers with 15 sufficient authority and empowerment to 16 carry out the duties they've been 17 assigned. And it also makes it very 18 difficult to figure out who is the 19 decisionmaker in those cases, which all 20 leads to effectiveness of the program. 21 Q. I take it that you would 22 give me the same answer to the question, 23 is spreading responsibility for 24 controlled substances compliance across</p>
<p style="text-align: right;">Page 491</p> <p>1 MR. BOGLE: She said 192. 2 BY MS. SWIFT: 3 Q. 192. 192. 4 A. I'm sorry. I misheard you. 5 Q. No, it's because I goofed 6 you up. 7 A. 192? 8 Q. Correct, sir. 9 A. All right. I'm at 192. 10 Q. This is Section 13.4.3 on 11 Walgreens' failures to designate a 12 high-level individual or group with sole 13 responsibility for controlled substances 14 compliance -- 15 A. Yes. 16 Q. -- or provide enough 17 resources for the group contributed to 18 its ineffective and dysfunctional 19 anti-diversion program, right, sir? 20 A. Yes, sir. 21 Q. You say in this section 22 that, "Responsibility for controlled 23 substances compliance was spread across 24 multiple departments as Walgreens</p>	<p style="text-align: right;">Page 493</p> <p>1 multiple departments a violation of the 2 DEA's suspicious order monitoring? 3 A. Yes, Counselor, I will give 4 you exactly the same answer, because 5 again -- 6 Q. That's great. That's all I 7 needed to know. 8 A. -- they're all linked 9 together. 10 Q. Turn to 193, please. At the 11 top of that page you say, "Walgreens 12 diffused responsibility and 13 accountability to an informal working 14 committee," correct? 15 A. That's what I've written, 16 yes. 17 Q. Is it your opinion that that 18 is a violation of either the Controlled 19 Substances Act or the DEA's suspicious 20 order monitoring regulation? 21 A. Again, what I'm talking 22 to -- what I was asked to look at, and 23 what I continually tell -- keep trying to 24 tell you that I was looking at, and you</p>

Page 494

1 keep wanting to go back to just the  
 2 controlled substances regulations and --  
 3 and all, and go no further. I was asked  
 4 to look at whether the program was  
 5 effective in my opinion. And in my  
 6 opinion, this is a symptom of an  
 7 ineffective program.  
 8 Q. I want to be very clear  
 9 here. You are absolutely right. I do  
 10 want to focus only on the Controlled  
 11 Substances Act and this DEA's suspicious  
 12 order monitoring regulation. Okay?  
 13 That's -- those -- that is what I'm  
 14 asking you questions about.  
 15 A. And I'm saying to you you  
 16 can't do that. From what I was asked to  
 17 do was look at effectiveness of a  
 18 program. And to do that they all --  
 19 these pieces all fit together.  
 20 Q. I understand that you did  
 21 more than that in your report. I am  
 22 entitled to an answer to my questions  
 23 which may be narrower than what's in your  
 24 report. Okay?

Page 495

1 A. And I'm trying to answer  
 2 your questions as best I can.  
 3 Q. So I'll ask again whether  
 4 it's your opinion, really truly focusing  
 5 only on the Controlled Substances Act and  
 6 the DEA's suspicious order monitoring  
 7 regulation, is it a violation to diffuse  
 8 responsibility and accountability to an  
 9 informal working committee?  
 10 A. And I'm saying to you,  
 11 Counselor, it's part and parcel of  
 12 looking at whether the program is  
 13 effective or not. And that's what I was  
 14 looking at.  
 15 Q. You testified a moment  
 16 ago -- you referred to the Russian  
 17 nesting dolls. Let's look at the Russian  
 18 nesting dolls.  
 19 A. Okay. Let's look at the  
 20 Russian nesting dolls.  
 21 Q. That's Page 7.  
 22 A. Yeah, I'm there.  
 23 Q. Is a fair reading of  
 24 Figure 1, which I'm going to refer to as

Page 496

1 the Russian nesting dolls because you do,  
 2 okay?  
 3 A. That's what I refer to it  
 4 as, yes.  
 5 Q. Is a fair reading of  
 6 Figure 1 that the suspicious order  
 7 monitoring regulation, 1301.74(b) is  
 8 represented by the smallest circle in  
 9 Figure 1?  
 10 A. Suspicious order monitoring  
 11 is represented by the smallest circle,  
 12 yes.  
 13 Q. And then you've got a bigger  
 14 circle around that circle for a  
 15 controlled substances program. Are you  
 16 trying to fit within that bigger circle  
 17 anything that would fall under the  
 18 Controlled Substances Act?  
 19 A. I'm talking about an overall  
 20 anti-diversion program. SOM is part of  
 21 an overall anti-diversion program. It's  
 22 not the only piece. It's a piece.  
 23 Q. Is it your testimony that  
 24 there is no way to distinguish from what

Page 497

1 would fit within the requirements of the  
 2 DEA's suspicious order monitoring program  
 3 from the rest of the work that you have  
 4 done with respect to compliance programs?  
 5 MR. BOGLE: Object to form.  
 6 THE WITNESS: I'm saying --  
 7 I'm saying they are all  
 8 interlinked is what I'm trying to  
 9 explain to you.  
 10 BY MS. SWIFT:  
 11 Q. And I'm asking whether it's  
 12 possible to unlink them.  
 13 A. I honestly do not believe  
 14 you can unlink them. I believe they are  
 15 linked together.  
 16 Q. Okay. Let's go back to 192.  
 17 A. I'm back there.  
 18 Q. All right. Actually I'm  
 19 going to skip ahead to page -- I think  
 20 it's 195.  
 21 195 talks about industry  
 22 guidelines.  
 23 Do you see that?  
 24 A. No. I'm not sure where you

Page 498	Page 500
<p>1 are.</p> <p>2 Q. The paragraph that starts,</p> <p>3 "This lack of documentation."</p> <p>4 A. Yes, okay.</p> <p>5 Q. You mention that that's</p> <p>6 contrary to industry guidelines as well.</p> <p>7 And then you say "HDMA in its 2008</p> <p>8 voluntary industry guidelines" --</p> <p>9 A. Right.</p> <p>10 Q. Do you know one way or</p> <p>11 another whether Walgreens has ever been a</p> <p>12 member of the HDMA?</p> <p>13 A. No, Counselor, I don't know</p> <p>14 one way or the other.</p> <p>15 Q. Did you check?</p> <p>16 A. No, I did not.</p> <p>17 Q. Do you know whether</p> <p>18 companies like Walgreens that are not</p> <p>19 HDMA members might have reasons for doing</p> <p>20 things a little differently than how HDMA</p> <p>21 members do things?</p> <p>22 A. Well --</p> <p>23 MR. BOGLE: Object to form.</p> <p>24 THE WITNESS: -- I think we</p>	<p>1 have good quality documentation. I think</p> <p>2 that's a requirement. Otherwise how can</p> <p>3 you know what you've done or not done?</p> <p>4 Q. Sir --</p> <p>5 A. I can --</p> <p>6 MR. BOGLE: Finish your</p> <p>7 answer. Are you done?</p> <p>8 THE WITNESS: I'm done.</p> <p>9 BY MS. SWIFT:</p> <p>10 Q. Do you know what the word</p> <p>11 diversion is?</p> <p>12 A. Yeah. If you want to get</p> <p>13 the precise definition we can go back to</p> <p>14 the front of the report.</p> <p>15 Q. I'd like to know if you can</p> <p>16 give me a definition of diversion without</p> <p>17 looking at something in your report.</p> <p>18 A. Again, to be absolutely</p> <p>19 precise, I would love to give you that.</p> <p>20 I'm going to go back to my report and</p> <p>21 rely on my report.</p> <p>22 Q. It doesn't have to be that</p> <p>23 precise.</p> <p>24 A. I'm going to rely on my</p>
Page 499	Page 501
<p>1 need to be clear that when we look</p> <p>2 at the HDMA guidelines in and of</p> <p>3 themselves, they, in fact, say</p> <p>4 they must be adapted for</p> <p>5 individual companies even among</p> <p>6 the same class, if we are talking</p> <p>7 about wholesale distributors.</p> <p>8 So again, I think you're --</p> <p>9 I think you're missing the point.</p> <p>10 The HDMA guidelines talk about</p> <p>11 good quality of documentation and</p> <p>12 the importance of good quality</p> <p>13 documentation and maintaining it.</p> <p>14 These are principles that</p> <p>15 certainly Walgreens could have</p> <p>16 employed.</p> <p>17 BY MS. SWIFT:</p> <p>18 Q. Could have -- you said could</p> <p>19 have employed.</p> <p>20 A. Could have.</p> <p>21 Q. Was -- was it required to</p> <p>22 employ?</p> <p>23 A. I believe if you want to</p> <p>24 call your program effective, you have to</p>	<p>1 report.</p> <p>2 MR. BOGLE: You can go to</p> <p>3 your report.</p> <p>4 THE WITNESS: I'm going to</p> <p>5 go with my --</p> <p>6 MS. SWIFT: I don't want to</p> <p>7 know the definition that he has in</p> <p>8 his report.</p> <p>9 BY MS. SWIFT:</p> <p>10 Q. What I would like to know is</p> <p>11 if you can give a definition without</p> <p>12 looking at your report. Yes or no?</p> <p>13 A. I'm going to look at my</p> <p>14 report.</p> <p>15 Q. Okay.</p> <p>16 A. I want to look at my report.</p> <p>17 Q. That's fine. We'll move on.</p> <p>18 A. Okay.</p> <p>19 Q. You haven't done any</p> <p>20 analysis of any order that Walgreens</p> <p>21 shipped to one of its pharmacies to</p> <p>22 determine whether that order led to drugs</p> <p>23 being diverted, correct, sir?</p> <p>24 A. Again, Counselor, I'm not</p>

Page 502

1 here to talk about whether or not there  
2 was diversion. What I'm talking about is  
3 you had a process into place. You didn't  
4 follow -- you didn't follow your process  
5 into place.  
6 You had poor documentation  
7 of the work that you did when you say you  
8 did due diligence. There's poor work  
9 that's there. And at the end of the day,  
10 it's hard to know what the heck you did.  
11 So I'm talking about the quality of your  
12 program.  
13 I'm not talking about  
14 whether -- whether -- I'm not talking  
15 about whether it led to diversion or not.  
16 I'm just talking about you've got --  
17 you've got a sloppy program.  
18 Q. Did you do any analysis to  
19 see how often a Walgreens store had an  
20 order rejected by a Walgreens  
21 distribution center and then went to an  
22 outside distributor to fill that order?  
23 MR. BOGLE: Object to form.  
24 BY MS. SWIFT:

Page 503

1 Q. Just yes or no, if you could  
2 please.  
3 MR. BOGLE: Answer how you  
4 see fit.  
5 THE WITNESS: Again, I've  
6 got to go back and look at exactly  
7 what I looked at, but...  
8 BY MS. SWIFT:  
9 Q. If you can't answer that  
10 without looking at your report, we'll  
11 move on. Turn to Page 206, please.  
12 Actually, let's go ahead and  
13 go to 208. We'll go back to that last  
14 paragraph in the Walgreens section.  
15 A. Sure.  
16 Q. The one about the crucial  
17 employees.  
18 A. Mm-hmm.  
19 Q. You wrote that it's your  
20 understanding that Natasha Polster, Ed  
21 Bratton and Rex Swords were the crucial  
22 employees involved in shaping,  
23 maintaining and operating Walgreens'  
24 anti-diversion program, correct?

Page 504

1 MR. BOGLE: Object to form.  
2 THE WITNESS: That's what I  
3 wrote.  
4 BY MS. SWIFT:  
5 Q. You say that these crucial  
6 employees continued in positions of  
7 substantial authority at Walgreens after  
8 the failure of its compliance program and  
9 that Walgreens failed to "hold these  
10 individuals accountable."  
11 Do you think that  
12 Ms. Polster, Mr. Bratton, and Mr. Swords  
13 should have been fired?  
14 A. No, I said they should be  
15 held accountable, Counselor.  
16 Q. Well, what do you mean by  
17 that? Do you think they should be  
18 demoted?  
19 A. Counselor, there are whole a  
20 lot of options to be looked at when you  
21 holding someone accountable. I did not  
22 specify a remedy.  
23 Q. And I'm asking you what you  
24 were thinking of for a remedy.

Page 505

1 A. I wasn't thinking of a  
2 precise remedy. I was thinking of just  
3 some form of accountability, which can  
4 range to anything from, you know, loss a  
5 bonus to demotion to transfer to  
6 termination. It's a range of factors. I  
7 wasn't making a judgment call as to a  
8 particular remedy. What I was saying was  
9 I didn't see any remedy.  
10 Q. Were you disciplined at C.R.  
11 Bard when that company pleaded guilty to  
12 hundreds of felonies while you were a  
13 lawyer there?  
14 A. I wasn't a lawyer there when  
15 they pleaded guilty to a hundred -- to  
16 the conduct -- when the conduct occurred.  
17 I came in on board afterwards to clean it  
18 up.  
19 Q. I'm going to ask you to take  
20 a look at what I will mark -- if I can  
21 have more stickers, please. We talked  
22 about the Chemical Handler's Manual a  
23 little bit today, right, sir.  
24 A. Yeah, we did. We had a

<p style="text-align: right;">Page 506</p> <p>1 conversation about it.</p> <p>2 Q. Is it your testimony that</p> <p>3 the Chemical Handler's Manual provides</p> <p>4 guidance to distributors of controlled</p> <p>5 substances?</p> <p>6 A. I'll say that one form of</p> <p>7 guidance that's provided by DEA, yes.</p> <p>8 Q. All right. Several times</p> <p>9 today, you've said that various portions</p> <p>10 of your report are based on your</p> <p>11 knowledge, your experience, your review</p> <p>12 of data in the case, conversations with</p> <p>13 Mr. Rafalski, and a number of times I</p> <p>14 noted on the transcript that you ended</p> <p>15 those answers with "et cetera."</p> <p>16 Do you recall that?</p> <p>17 A. I do recall that.</p> <p>18 Q. What are you including in</p> <p>19 the "et cetera"?</p> <p>20 A. Publicly available</p> <p>21 documents. The list of what I looked at</p> <p>22 and some of the things that I relied on</p> <p>23 are in the front of the report. We can</p> <p>24 go down that list in detail if you'd</p>	<p style="text-align: right;">Page 508</p> <p>1 A. Yes.</p> <p>2 Q. Do you have any idea whether</p> <p>3 Mr. Williams is still licensed?</p> <p>4 A. No, ma'am, I don't.</p> <p>5 Q. Do you have any idea whether</p> <p>6 Mr. Williams has ever been disciplined?</p> <p>7 A. No, ma'am, I don't.</p> <p>8 Q. Turn to Page 50, please. In</p> <p>9 the very last sentence on Page 50, you</p> <p>10 make a reference to Dr. Patel.</p> <p>11 Do you see that?</p> <p>12 A. I do see the reference to</p> <p>13 Dr. Patel.</p> <p>14 Q. Do you know whether</p> <p>15 Dr. Patel has ever lost his license?</p> <p>16 A. Again, I do not. But it was</p> <p>17 not germane to this discussion. But what</p> <p>18 we're talking about here is the fact that</p> <p>19 80 percent of the oxycodone prescriptions</p> <p>20 for that period of time were coming from</p> <p>21 a single physician. That should have</p> <p>22 triggered a red flag with somebody.</p> <p>23 Somebody should have done some digging.</p> <p>24 Q. Do you know --</p>
<p style="text-align: right;">Page 507</p> <p>1 like.</p> <p>2 Q. We'd need to look at the</p> <p>3 footnotes --</p> <p>4 A. No, we'd need to look at --</p> <p>5 Q. -- in what you've actually</p> <p>6 supported?</p> <p>7 A. No. We look at the front.</p> <p>8 I told you some of the things -- the list</p> <p>9 of things that I relied upon is in the</p> <p>10 front too.</p> <p>11 Q. Okay.</p> <p>12 A. General categories is what</p> <p>13 you're looking for.</p> <p>14 Q. All right. I'm going to try</p> <p>15 to wrap it up here.</p> <p>16 On Page 49 in the section on</p> <p>17 Euclid Family Pharmacy.</p> <p>18 A. Okay.</p> <p>19 Q. Are you there?</p> <p>20 A. I think so.</p> <p>21 Q. You make reference to a</p> <p>22 Timothy Williams, a licensed Ohio</p> <p>23 pharmacist in the first paragraph.</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 509</p> <p>1 A. That's all I'm saying.</p> <p>2 Q. Do you know whether</p> <p>3 Dr. Patel was ever disciplined?</p> <p>4 A. No, Counselor. But, again,</p> <p>5 it wasn't germane to the discussion,</p> <p>6 again, as we talked about. What we're</p> <p>7 talking about is the percentage of</p> <p>8 business coming in from a single doctor</p> <p>9 should have triggered somebody to look.</p> <p>10 Q. Can you look at Exhibit 5</p> <p>11 for me, please.</p> <p>12 A. Yep.</p> <p>13 Q. Turn if you would, please,</p> <p>14 to Page 22.</p> <p>15 A. Page 22.</p> <p>16 Q. Are you there? This is a</p> <p>17 section entitled "Wholesale</p> <p>18 Distributors."</p> <p>19 Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. It says -- this is the</p> <p>22 suspicious order task force report from</p> <p>23 1998, correct, sir?</p> <p>24 A. That's what it appears to</p>



<p style="text-align: right;">Page 510</p> <p>1 be, yes.</p> <p>2 Q. You talk about this report</p> <p>3 in your report?</p> <p>4 A. Briefly, yes.</p> <p>5 Q. Page 22 says that, "The</p> <p>6 suspicious orders task force recommends</p> <p>7 that those in the wholesale drug</p> <p>8 distribution supply chain who are able to</p> <p>9 use the DEA-approved suspicious order</p> <p>10 monitoring system in use by wholesale</p> <p>11 drug distributors for controlled</p> <p>12 substances as enhanced by the task force</p> <p>13 in Appendix A, Exhibit 2, for the</p> <p>14 reporting of potentially suspicious</p> <p>15 orders of listed chemicals, including</p> <p>16 ephedrine, pseudoephedrine, and</p> <p>17 phenylpropylamine," correct?</p> <p>18 A. Yes.</p> <p>19 Q. Then it goes on to say that,</p> <p>20 "DEA will be responsible, upon subsequent</p> <p>21 industry request, for providing certain</p> <p>22 other data necessary to support the</p> <p>23 baseline suspicious order monitoring</p> <p>24 system for listed chemicals analogous to</p>	<p style="text-align: right;">Page 512</p> <p>1 average purchases or other DEA-approved</p> <p>2 methods will be used to identify orders</p> <p>3 which could be considered excessive or</p> <p>4 suspicious."</p> <p>5 That's what it says?</p> <p>6 A. Yes, that's what it says.</p> <p>7 Q. Then it says, "This is</p> <p>8 basically what is done for Schedules II</p> <p>9 through V controlled substances, for</p> <p>10 which base code ingredient and/or gram</p> <p>11 weight equivalent information is not</p> <p>12 available from DEA," correct?</p> <p>13 A. That's, again, what it says.</p> <p>14 Q. All right. I have I think</p> <p>15 one more question for you. I'm going to</p> <p>16 mark the Chemical Handler's Manual as</p> <p>17 Exhibit 13.</p> <p>18 (Document marked for</p> <p>19 identification as Exhibit</p> <p>20 Whitelaw-13.)</p> <p>21 BY MS. SWIFT:</p> <p>22 Q. I'll hand you a copy of it.</p> <p>23 You testified earlier today</p> <p>24 that the Chemical Handler's Manual</p>
<p style="text-align: right;">Page 511</p> <p>1 that that's currently in use to monitor</p> <p>2 controlled substance orders." Correct,</p> <p>3 sir?</p> <p>4 A. Yes, I see that.</p> <p>5 MR. BOGLE: Object to form.</p> <p>6 I think you've missed some words</p> <p>7 there. But go ahead.</p> <p>8 BY MS. SWIFT:</p> <p>9 Q. Then it says, "For</p> <p>10 registrants in this supply chain who do</p> <p>11 not choose to use this data" -- and I'm</p> <p>12 skipping ahead -- "other DEA approved</p> <p>13 methods will be used to identify orders</p> <p>14 which could be considered excessive or</p> <p>15 suspicious." Correct?</p> <p>16 A. I'm sorry, Counselor, can</p> <p>17 you go back again? Because you -- by</p> <p>18 skipping words, I'm not sure -- you</p> <p>19 had --</p> <p>20 Q. I'll just read the sentence.</p> <p>21 A. That'd be great.</p> <p>22 Q. "For registrants in this</p> <p>23 supply chain who do not choose to use</p> <p>24 this data, customer and customer category</p>	<p style="text-align: right;">Page 513</p> <p>1 instructs registrants to block orders.</p> <p>2 I'd like you to tell me where.</p> <p>3 A. All right. I'll read it for</p> <p>4 you and find it for you, Counselor.</p> <p>5 MS. SWIFT: I'll note for</p> <p>6 the record that we've been looking</p> <p>7 for, I don't know, a minute or</p> <p>8 two. It's 7:15 p.m.</p> <p>9 THE WITNESS: This is the</p> <p>10 section that you're looking for,</p> <p>11 Counselor, is on 19.</p> <p>12 BY MS. SWIFT:</p> <p>13 Q. Tell me what you're</p> <p>14 referring to.</p> <p>15 A. I'm referring to the</p> <p>16 paragraph that starts, "When a regulated</p> <p>17 person suspects that an order may be</p> <p>18 intended for illicit purposes, good</p> <p>19 practice requires that every reasonably</p> <p>20 effort" -- "every reasonable effort be</p> <p>21 made to resolve those suspicions."</p> <p>22 Q. Okay. Thank you.</p> <p>23 MR. BOGLE: Are you done?</p> <p>24 THE WITNESS: No, I was not.</p>

Page 514	Page 516
<p>1 MR. BOGLE: Then keep 2 reading. 3 THE WITNESS: "In addition 4 to making the required reports, 5 the transaction should not be 6 completed until the customer is 7 able to eliminate the suspicions. 8 The distributor may have to forgo 9 some transactions. When DEA 10 reviews the distributor decisions, 11 minor events are not cause for 12 government action. At the same 13 time, a regulated person who fails 14 to implement a system to prevent 15 diversion will be closely 16 scrutinized and, if warranted, may 17 be subject to civil, 18 administrative, and criminal 19 penalties." 20 BY MS. SWIFT: 21 Q. It is -- is it your 22 testimony that everything that's in the 23 Chemical Handler's Manual applies to 24 distributors of controlled substances?</p>	<p>1 evening. My name is Lauren Fincher, and 2 I represent Henry Schein Inc. and Henry 3 Schein Medical Systems, Inc. 4 And I think this should be 5 very quick so we can get you out of here. 6 Dr. Whitelaw, do you have 7 any opinions regarding Henry Schein, 8 Inc.? 9 A. Counselor, no, I do not. 10 I -- I did not finish my work on -- or 11 finish work on Henry Schein to formulate 12 those opinions. 13 Q. And, Dr. Whitelaw, I 14 appreciate that. And I understand from 15 your earlier testimony that you made a 16 pitch for Henry Schein work while you 17 were at Deloitte, correct? 18 A. Yes, Counselor, that is 19 correct. 20 Q. And is that what you were 21 referring to a moment ago? 22 A. No. I was referring to the 23 fact that it wasn't -- Henry Schein was 24 not one of the defendants I looked at for</p>
Page 515	Page 517
<p>1 MR. BOGLE: Object to form. 2 THE WITNESS: I'm saying 3 that everything in the Chemical 4 Handler's Manual should be taken 5 into account and factored in to an 6 effective compliance program. 7 Again, what you all have 8 been complaining about is you 9 don't have enough guidance. I 10 would say that this is pretty 11 clear guidance of what is being 12 expected. 13 MS. SWIFT: I don't have any 14 further questions. 15 THE VIDEOGRAPHER: Going off 16 the record at 7:18 p.m. 17 (Brief recess.) 18 THE VIDEOGRAPHER: We are 19 back on the record at 7:19 p.m. 20 - - - 21 EXAMINATION 22 - - - 23 BY MS. FINCHER: 24 Q. Great. Dr. Whitelaw, good</p>	<p>1 the basis for this report. And, 2 therefore, I haven't come to no 3 conclusions about your suspicious order 4 monitoring program. That -- that's what 5 I thought you were asking. 6 Q. It is. So just to confirm, 7 Dr. Whitelaw, you don't have any opinions 8 regarding Henry Schein Inc., correct? 9 A. Not at this moment in time 10 that pertain to the work that I did in 11 this report, no. 12 Q. And do you have any opinions 13 regarding Henry Schein Medical Systems 14 Inc.? 15 A. Again, same -- same answers 16 to the questions, Counselor. I didn't -- 17 you know, they are not included in this 18 report, therefore, I'm not going to draw 19 any opinions. I have no opinions to 20 draw. 21 Q. Okay. Great. 22 MS. FINCHER: Thank you. 23 That's all the questions I have. 24 THE VIDEOGRAPHER: Going off</p>

<p style="text-align: right;">Page 518</p> <p>1 the record at 7:21 p.m.  2 (Excused.)  3 (Deposition adjourned at  4 approximately 7:21 p.m.)  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20  21  22  23  24</p>	<p style="text-align: right;">Page 520</p> <p>1 INSTRUCTIONS TO WITNESS  2  3 Please read your deposition  4 over carefully and make any necessary  5 corrections. You should state the reason  6 in the appropriate space on the errata  7 sheet for any corrections that are made.  8 After doing so, please sign  9 the errata sheet and date it.  10 You are signing same subject  11 to the changes you have noted on the  12 errata sheet, which will be attached to  13 your deposition.  14 It is imperative that you  15 return the original errata sheet to the  16 deposing attorney within thirty (30) days  17 of receipt of the deposition transcript  18 by you. If you fail to do so, the  19 deposition transcript may be deemed to be  20 accurate and may be used in court.  21  22  23  24</p>
<p style="text-align: right;">Page 519</p> <p>1  2 CERTIFICATE  3  4  5 I HEREBY CERTIFY that the  6 witness was duly sworn by me and that the  7 deposition is a true record of the  8 testimony given by the witness.  9  10 It was requested before  11 completion of the deposition that the  12 witness, DR. SETH B. WHITE LAW , have the  13 opportunity to read and sign the  14 deposition transcript.  15  16  17  18  19  20  21  22  23  24</p> <p>MICHELLE L. GRAY,  A Registered Professional  Reporter, Certified Shorthand  Reporter, Certified Realtime  Reporter and Notary Public  Dated: May 17, 2019</p> <p>(The foregoing certification  of this transcript does not apply to any  reproduction of the same by any means,  unless under the direct control and/or  supervision of the certifying reporter.)</p>	<p style="text-align: right;">Page 521</p> <p>1 - - - - -  2 E R R A T A  3 - - - - -  4 PAGE LINE CHANGE  5  6 REASON: _____  7  8 REASON: _____  9  10 REASON: _____  11  12 REASON: _____  13  14 REASON: _____  15  16 REASON: _____  17  18 REASON: _____  19  20 REASON: _____  21  22 REASON: _____  23  24 REASON: _____</p>

Page 522

ACKNOWLEDGMENT OF DEPONENT

I, \_\_\_\_\_, do  
hereby certify that I have read the  
foregoing pages, 1 - 523, and that the  
same is a correct transcription of the  
answers given by me to the questions  
therein propounded, except for the  
corrections or changes in form or  
substance, if any, noted in the attached  
Errata Sheet.

\_\_\_\_\_  
DR. SETH B. WHITE LAW                      DATE

Subscribed and sworn  
to before me this  
\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.  
My commission expires: \_\_\_\_\_

\_\_\_\_\_  
Notary Public

Page 523

LAWYER'S NOTES

PAGE LINE

1	_____	_____	_____
2	_____	_____	_____
3	_____	_____	_____
4	_____	_____	_____
5	_____	_____	_____
6	_____	_____	_____
7	_____	_____	_____
8	_____	_____	_____
9	_____	_____	_____
10	_____	_____	_____
11	_____	_____	_____
12	_____	_____	_____
13	_____	_____	_____
14	_____	_____	_____
15	_____	_____	_____
16	_____	_____	_____
17	_____	_____	_____
18	_____	_____	_____
19	_____	_____	_____
20	_____	_____	_____
21	_____	_____	_____
22	_____	_____	_____
23	_____	_____	_____
24	_____	_____	_____